IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No.:

5,254,556

Issued:

October 19, 1993

Expiration Date:

October 27, 2009

Inventors:

Cornelus G. M. Janssen, Alfonsus G. Knaeps, Ludo E. J. Kennis, Jan Vandenberk

Title:

3-PIPERIDINYL-1,2-BENZISOXAZOLES

RECEIVED

Mail Stop Patent Extension Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 JUL 07 2009

PATENT EXTENSION

TRANSMITTAL OF APPLICATION FOR INTERIM EXTENSION OF PATENT TERM (37 C.F.R. § 1.790)

Attached hereto is an Application for Interim Extension of Patent Term for the above-identified Patent along with (5) copies. In such Petition, Applicant provides the following sections and exhibits.

- I. SIGNATURE REQUIREMENTS (37 C.F.R. §1.730)
 - A. IDENTIFICATION OF PERSON(S) SUBMITTING THE APPLICATION
 - B. RECORDAL OF ASSIGNMENT IN PTO
- II. APPLICATION REQUIREMENTS (37 C.F.R. §§1.790 and 1.740)
 - A. IDENTIFICATION OF PRODUCT UNDERGOING REGULATORY REVIEW (1.740(a)(1))
 - B. IDENTIFICATION OF THE FEDERAL STATUTE UNDER WHICH REGULATORY REVIEW IS CURRENTLY TAKING PLACE (1.740(a)(2))
 - C. IDENTIFICATION OF ACTIVE INGREDIENTS AND PREVIOUS APPROVAL INFORMATION (1.740(a)(4))
 - D. IDENTIFICATION OF PATENT (1.740(a)(6), (7), (8))
 - E. IDENTIFICATION OF CLAIMS READING ON THE PRODUCT SEEKING APPROVAL(1.740(a)(9))
 - F. RELEVANT DATES AND INFORMATION (1.740(a)(10))
 - G. DESCRIPTION OF SIGNIFICANT ACTIVITIES OF APPLICANT DURING REGULATORY REVIEW (1.740(a)(11))
 - H. STATEMENT THAT PATENT IS ELIGIBLE FOR EXTENSION (1.740(a)(12))

I. ACKNOWLEDGEMENT OF DUTY OF DISCLOSURE (1.740(a)(13))

J. FEE (1.740(a)(14))

K. CORRESPONDENCE

L. COPIES (§ MPEP 2753 (8th Edition, Rev. No. 7))

Exhibit 1 Copy of Merger Documents

Exhibit 2 Copy of U.S. Patent No. 5.254.556

Exhibit 3 Copy of U.S. Patent & Trademark

Office Maintenance Fee Statement for U.S. Patent No. 5,254,556____

Exhibit 4 Copy of Terminal Disclaimer filed in

U.S. Patent No. 5,254,556

Exhibit 5 Claims 1, 2 and 3 of U.S. Patent No. 5254,556

Read on the Active Ingredient of the Product

Seeking Approval or its Method of Use

Exhibit 6 Description of Significant Activities of

Applicant during Regulatory Review

Victoria Messenger

(703) 330-6011

Schellin & Associates, Ltd.

1940 Duke Street

Suite 200

Arlington, VA 22202

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No.:

5,254,556

Issued:

October 19, 1993

Expiration Date:

October 27, 2009

Inventors:

Cornelus G. M. Janssen, Alfonsus G. Knaeps, Ludo E. J. Kennis, Jan Vandenberk

Title:

3-PIPERIDINYL-1,2-BENZISOXAZOLES

Mail Stop Patent Extension Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 PATENT EXTENSION

APPLICATION FOR INTERIM EXTENSION OF PATENT TERM (37 C.F.R. § 1.790)

Pursuant to 35 U.S.C. §156(d) and 37 C.F.R. § 1.790, Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("Applicant") as Assignee and patent owner of the above-captioned patent, hereby petitions for an interim extension of U.S. Patent No. 5,254,556 (the '556 Patent). In support of such Petition, Applicant provides the following information:

I. SIGNATURE REQUIREMENTS (37 C.F.R. §1.730)

A. IDENTIFICATION OF PERSON(S) SUBMITTING THE APPLICATION

I, Hal Brent Woodrow, represent that I am a registered patent practitioner signing on behalf of the patent owner.

B. RECORDAL OF ASSIGNMENT IN PTO

This application, U.S.S.N. 07/932,142, filed August 19, 1992, which is a Divisional of U.S.S.N. 07/422,847, filed October 17, 1989, now issued as US Patent No. 5,158,952, which is a Continuation-in-Part of U.S.S.N. 07/267,857, filed November 7, 1988, which was abandoned. An assignment of U.S.S.N. 07/422,847 was recorded: Date: November 13, 1989 at Reel/Frame: 05171/0567 847from the named inventors to Janssen Pharmaceutica, N.V., and an assignment of U.S.S.N. 07/422,847 was recorded: Date: October 4, 2006 at Reel/Frame: 018385/0112 from Janssen Pharmaceutica, N.V. to Janssen L.P; which was dissolved by the Limited Partner, Janssen, Inc., and General Partner Janssen Pharmaceutica Inc., when they merged and subsequently became Ortho-McNeil-Janssen Pharmaceuticals, Inc. were recorded in U.S.S.N. 07/422,847: Date: May 20, 2009 at Reel/Frame: 022708/0352 (copies of the merger documents are attached as Exhibit 1). Additionally to further clarify the record US Patent No. 5,254,556 was specifically assigned to Ortho-McNeil-Janssen Pharmaceuticals, Inc. on July 6th, 2009.

II. APPLICATION REQUIREMENTS (37 C.F.R. §§ 1.790 and 1.740)

A. IDENTIFICATION OF PRODUCT UNDERGOING REGULATORY REVIEW (1.740(a)(1))

The United States Food and Drug Administration ("FDA") is currently reviewing New Drug Application ("NDA") No. 22-264 for INVEGA SUSTENNATM (paliperidone palmitate). The active ingredient of INVEGA SUSTENNA is paliperidone palmitate. The chemical name for paliperidone palmitate is [(9RS)-3-[2-[4-(6-fluoro-1,2-benzoxazol-3-yl)piperidin-1-yl]ethyl]-2-methyl-4-oxo-6,7,8,9-tetrahydropyrido[1,2-a]pyrimidin-9-yl] hexadecanoate, also known as C_{16} alkanoic acid ester of 3-[2-[4-(6-fluoro-1,2-benzisoxazol-3-yl)-1-piperidinyl]ethyl]- 6,7,8,9-tetrahydro-9-hydroxy-2-methyl-4H-pyrido[1,2-a]pyrimidin-4-one.

Paliperidone palmitate has the following structural formula:

B. IDENTIFICATION OF THE FEDERAL STATUTE UNDER WHICH REGULATORY REVIEW IS CURRENTLY TAKING PLACE (1.740(a)(2))

Regulatory review for this product is currently occurring under the Federal Food Drug & Cosmetic Act, §505(b), 21 U.S.C. §355 (new drugs).

C. IDENTIFICATION OF ACTIVE INGREDIENTS AND PREVIOUS APPROVAL INFORMATION (1.740(a)(4))

INVEGA SUSTENNA is a human drug product, the sole active ingredient of which is paliperidone palmitate. Neither paliperidone palmitate, nor any salt or ester thereof, has been previously approved, alone or in combination, for commercial marketing or use under the Food, Drug & Cosmetic Act, the Public Health Service Act, or the Virus-Serum-Toxin Act.

D. IDENTIFICATION OF PATENT (1.740(a)(6), (7), (8))

Name of inventors: Cornelus G. M. Janssen

Alfonsus G. Knaeps Ludo E. J. Kennis Jan Vandenberk

Patent No.:

5,254,556

Date of issue:

October 19, 1993

Expiration date:

October 27, 2009

A copy of the patent, including the entire specification (with claims) and drawings is attached as Exhibit 2.

A copy of the U.S. Patent & Trademark Office Maintenance Fee Statement is attached as Exhibit 3.

A terminal disclaimer pursuant to 37 C.F.R. §1.321(a) was filed in the '556 Patent disclaiming the terminal part of the statutory term of any patent which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. §§154-156 and 173 of U.S. Patent No. 5,158,952. A copy of the disclaimer is attached as Exhibit 4. The '556 Patent remains commonly owned with U.S. Patent No. 5,158,952.

No certificate of correction or reexamination certificate has issued in the '556 Patent.

E. IDENTIFICATION OF CLAIMS READING ON THE PRODUCT SEEKING APPROVAL (1.740(a)(9))

The '556 Patent claims the active ingredient of the Product currently undergoing regulatory review which is paliperidone palmitate. The '556 Patent includes 6 claims, of which Claims 1 and 2 claim the Product, and Claim 3 claims the use of the Product.

A claim chart that lists each applicable claim of the '556 Patent and demonstrates the manner in which each claim reads on the Product is attached as Exhibit 5.

F. RELEVANT DATES AND INFORMATION (1.740(a)(10))

The '556 Patent claims a human drug.

The effective date of the investigational new drug (IND) application was June 2, 2003 and the IND No. is 67,356.

The new drug application (NDA) was initially submitted on October 26, 2007. The NDA No. is 22-264.

The NDA is currently undergoing regulatory review by the FDA.

G. DESCRIPTION OF SIGNIFICANT ACTIVITIES OF APPLICANT DURING REGULATORY REVIEW (1.740(a)(11)

Attached as Exhibit 6 is a "DESCRIPTION OF SIGNIFICANT ACTIVITES OF APPLICANT DURING REGULATORY REVIEW (1.740(a)(11))" that provides a description of the significant activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved Product and the significant dates applicable to such activities.

H. STATEMENT THAT PATENT IS ELIGIBLE FOR EXTENSION (1.740(a)(12))

To the best of my knowledge, the '556 Patent meets all the eligibility criteria set forth in 37 CFR 1.710 and 1.720 for extension of patent term. It is not possible to determine the length of the extension that will ultimately be claimed since approval has not yet been granted for the product. Applicant expects the regulatory review period to extend past the expiration of the '556 patent, and is therefore requesting an interim extension for a period of one year, pursuant to 37 CFR 1.790(a).

I. ACKNOWLEDGEMENT OF DUTY OF DISCLOSURE (1.740(a)(13))

I, Hal Brent Woodrow, the person signing below, acknowledge the duty to disclose to the Director of the U.S. Patent and Trademark Office and to the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension which is being sought herein.

J. FEE (1.740(a)(14))

The Application fee due is \$420.00 (37 C.F.R. § 1.740(a)(14) and § 1.20(j)(2).

Authorization is hereby made to charge the amount of \$420.00 to Deposit Account No. 10-0750/JAB0828USDIV/HBW.

Please also charge any additional fees required by this paper or credit any overpayment to Deposit Account No. 10-0750/JAB0828USDIV/HBW.

K. CORRESPONDENCE

Please direct all inquiries and correspondence relating to this application to:

Philip S. Johnson, Esq. Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933

Attn: Hal B. Woodrow Phone: (732) 524-2976 Facsimile: (732) 524-2808

L. COPIES (§ MPEP 2753 (8th Edition, Rev. No. 7).

Four additional copies of this application are attached, making a total of five copies being submitted.

Date: 6 July 2009

Hal Bout Woodhow

Hal Brent Woodrow Registration No. 32,501 Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933 Tel. No. 732-524-2976 Customer No. 27777

5/20/2009 9:48:38 PM PAGE 2/005 Fax Server

O:PHILIP S. JOHNSON COMPANY: ONE JOHNSON & JOHNSON PLAZA



United States Patent and Trademark Office

UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE



500864728A

MAY 20, 2009

PTAS

S

PHILIP S. JOHNSON ONE JOHNSON & JOHNSON PLAZA JOHNSON & JOHNSON NEW BRUNSWICK, NJ 08933

UNITED STATES PATENT AND TRADEMARK OFFICE NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AVAILABLE AT THE ASSIGNMENT SEARCH ROOM ON THE REEL AND FRAME NUMBER REFERENCED BELOW.

PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT AND TRADEMARK ASSIGNMENT SYSTEM. IF YOU SHOULD FIND ANY ERRORS OR HAVE QUESTIONS CONCERNING THIS NOTICE, YOU MAY CONTACT THE EMPLOYEE WHOSE NAME APPEARS ON THIS NOTICE AT 571-272-3350. PLEASE SEND REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, MAIL STOP: ASSIGNMENT SERVICES BRANCH, P.O. BOX 1450, ALEXANDRIA, VA 22313.

RECORDATION DATE: 05/20/2009

REEL/FRAME: 022708/0352 NUMBER OF PAGES: 10

BRIEF: MERGER (SEE DOCUMENT FOR DETAILS).

DOCKET NUMBER: JABO650USA

ASSIGNOR:

JANSSEN, INC. THE LIMITED PARTNER DOC DATE: 12/31/2007

OF JANSSEN, L.P.

ASSIGNEE:

ORTHO-MCNEIL-JANSSEN
PHARMACEUTICALS, INC.
1125 TRENTON-HARBOURTON ROAD
TITUSVILLE, NEW JERSEY 08560

SERIAL NUMBER: 07422847 PATENT NUMBER: 5158952 FILING DATE: 10/17/1989 ISSUE DATE: 10/27/1992

TITLE: 3-[2-[4-(6-FLUORO-1, 2-BENZISOXAZOL-3-YL)-1-PIPERDINYL]ETHYL]-6,7,8,9 TETRAHYDRO-9-HYDROXY-2-METHYL-4H-PYRIDO [1,2-A] PYRIMIDIN-4-ONE,

COMPOSITONS AND METHOD OF USE

5/20/2009 9:48:38 PM PAGE 3/005 Fax Server

O:PHILIP S. JOHNSON COMPANY: ONE JOHNSON & JOHNSON PLAZA

022708/0352 PAGE 2

ASSIGNMENT SERVICES BRANCH PUBLIC RECORDS DIVISION

5/20/2009 9:48:38 PM

MERGER

12/31/2007

PAGE

4/005

Fax Server

O:PHILIP S. JOHNSON COMPANY: ONE JOHNSON & JOHNSON PLAZA

PATENT ASSIGNMENT

Electronic Version v1.1

05/20/2009 500864728

Stylesheet Version v1.1 500864728

SUBMISSION TYPE: NEW ASSIGNMENT

	·
CONVEYING	PARTY DATA

EFFECTIVE DATE:

NATURE OF CONVEYANCE:

T T T T T T T T T T T T T T T T T T T	
Name	Execution Date
Janssen, Inc. the Limited Partner of Janssen, L.P.	12/31/2007

RECEIVING PARTY DATA

Name:	Ortho-McNeil-Janssen Pharmaceuticals, Inc.	
Street Address:	1125 Trenton-Harbourton Road	
City:	Titusville	
State/Country:	NEW JERSEY	
Postal Code:	08560	

PROPERTY NUMBERS Total: 1

Patent Number: 5156952	2

CORRESPONDENCE DATA

Fax Number:

(732)524-2808

Correspondence will be sent via US Mail when the fax attempt is unsuccessful.

Phone:

7816747816

Email:

JNJUSPATENT@CORUS.JNJ.COM

Correspondent Name:

Philip S. Johnson

Address Line 1:

One Johnson & Johnson Plaza

Address Line 2:

Johnson & Jahnson

Address Line 4:

New Brunswick, NEW JERSEY 08933

ATTORNEY DOCKET NUMBER: JAB0650USA

NAME OF SUBMITTER: Kristin Mele

Total Attachments: 8

source=Merger Docs for 3542a#page 1.tif

5/20/2009 9:48:38 PM

PAGE

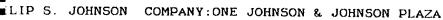
5/005

Fax Server

O:PHILIP S. JOHNSON COMPANY: ONE JOHNSON & JOHNSON PLAZA

source=Merger Docs for 3542a#page2.tif source=Merger Docs for 3542a#page3.tif source=Merger Docs for 3542a#page4.tif source=Merger Docs for 3542a#page5.tif source=Merger Docs for 3542a#page6.tif source=Merger Docs for 3542a#page7.tif source=Merger Docs for 3542a#page8.tif

1/005





UNITED STATES PATENT AND TRADEMARK OFFICE

Facsimile Transmission

To:

Name:

PHILIP S. JOHNSON

Company:

ONE JOHNSON & JOHNSON PLAZA

Fax Number:

17325242808

Voice Phone:

From:

Name:

ASSIGNMENT SERVICES BRANCH

Voice Phone: 571-272-3350

37 C.F.R. 1.6 sets forth the types of correspondence that can be communicated to the Patent and Trademark Office via facsimile transmissions. Applicants are advised to use the certificate of facsimile transmission procedures when submitting a reply to a non-final or final Office action by facsimile (37 CFR 1.8(a)).

Fax Notes:

Pg# Description

1 Cover Page

2 636.TXT

4 Document 1, Batch 1667777

J&JPAT DKT SECTION

USPTO ASSIGNMENT SYSTEM PROCESSING

Date and time of transmission: Wednesday, May 20, 2009 9:48:26 PM

Number of pages including this cover sheet: 05

JANSSEN, L.P.

In accordance with the Limited Partnership Agreement of Janssen, L.P., a New Jersey limited partnership, the undersigned, do hereby approve of the following:

WHEREAS, Janssen Inc. and Janssen Pharmaceutica Inc., are the limited partner and general partner, respectively, of this limited partnership,

WHEREAS, Janssen Inc. wishes to merge with and into Janssen Pharmaceutica Inc., thereby dissolving the limited partnership and filing a certificate of cancellation with the Secretary of State of New Jeresey.

NOW, THEREFORE, BE IT RESOLVED, that by virtue of the merger, this limited partnership is hereby dissolved, and further

RESOLVED, that a certificate of cancellation be and hereby is filed with the Secretary of State of New Jersey, effective as of December 31, 2007.

Limited Partie

Douglas K. Chia, Vice President

Janssen Pharmaceutica Inc. General Partner

Michael C. Chester, Secretary

Effective Date: December 30, 2007

Fax: CT CORPORATION

Dec 26 2007 11:42am P004/010 PAGE 82/92

> CAN FILED DEC 2 4 2007

0600011008

LP-103 (10/94)

New Jersey Division of Revenue

Certificate of Cancellation of a Limited Partnership

(Title NJSA 42:2A - 18)

1. Name of Limited Partnership:

Janssen, L.P.

2. Limited Partnership Number:

0600071008

Date of filing the Certificate of Limited Partnership:

July 1, 1999

4. The Reasons for filing the Certificate of Cancallation are:

The Limited Partnership no longer has assets and is no longer conducting business.

5. The effective date of this Certificate of Cancellation is December 31, 2007.

A Certificate of Cancellation must be signed by all General Partners.

Ortho-McNeil-Janssen Pharmaceuticals, Inc. (General Partner)

Signature James R. Hilton, Vice President

Date: 12/19/57

- I

Date:

Signature

Date:

Signature

Date:

Signature

Date:

Signature

Date:

(If more space is needed, attach an additional sheet)

51945806

73628712-NJ Division of Revenue, PO Box 308, Tremon, NJ 08625

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
CORPORATION BUREAU
206 NORTH OFFICE BUILDING
P.O. BOX 8722
HARRISBURG, PA 17105-8722
WWW.CORPORATIONS.STATE.PA.US/CORP

Ortho-McNeil-Janssen Pharmaceuticals, Inc.

THE CORPORATION BUREAU IS HAPPY TO SEND YOU YOUR FILED DOCUMENT. THE CORPORATION BUREAU IS HERE TO SERVE YOU AND WANTS TO THANK YOU FOR DOING BUSINESS IN PENNSYLVANIA.

IF YOU HAVE ANY QUESTIONS PERTAINING TO THE CORPORATION BUREAU, PLEASE VISIT OUR WEB SITE LOCATED AT <u>WWW.CORPORATIONS.STATE.PA.US/CORP</u> OR PLEASE CALL OUR MAIN INFORMATION TELEPHONE NUMBER (717)787-1057. FOR ADDITIONAL INFORMATION REGARDING BUSINESS AND / OR UCC FILINGS, PLEASE VISIT OUR ONLINE "SEARCHABLE DATABASE" LOCATED ON OUR WEB SITE.

ENTITY NUMBER: 681308

CT CORPORATION SYSTEM 100 Pine Street, Suite 325 Harrisburg, PA 17101

Entity #: 681306 Date Filed: 12/18/2007 Effective Date: 12/31/2007 Pedro A. Cortés recretary of the Commonwealth

Articles of Amendment-Domestic Corporation (15 Pa.C.S.)			
Business Corporation Nonprofit Corporation			
Adding CT CORP-COUNTER City CT CORP-COUNTER Zin Code	Document will be return name and address you the left.		
\$70		T07/35384123	
		, , , , , , , , , , , , , , , , , , ,	
2. The (a) address of this corporation's current registered off commercial registered office provider and the county of vicorrect the following information to conform to the record	enue is (the Department is hereby	ame of its	
2 The (a) address of this corporation's current registered off	enue is (the Department is hereby	ame of its suthorized to County	
The (s) address of this corporation's current registered off commercial registered office provider and the county of vicerrect the following information to conform to the record	enue is (the Department is hereby is of the Department):	authorized to	
2. The (a) address of this corporation's current registered off commercial registered office provider and the county of vicorrect the following information to conform to the record (a) Number and Street City (b) Name of Commercial Registered Office Provider	enue is (the Department is hereby is of the Department): State Zip Alleghany	County	
2. The (s) address of this corporation's current registered off commercial registered office provider and the county of we correct the following information to conform to the record (a) Number and Street City (b) Name of Commercial Registered Office Provider C/O CT Corporation System	enue is (the Department is hereby is of the Department): State Zip Alleghany	County	
2. The (a) address of this corporation's current registered off commercial registered office provider and the county of we correct the following information to conform to the record (a) Number and Street City (b) Name of Commercial Registered Office Provider c/o CT Corporation System 3. The statute by or under which it was incorporated: Section	enue is (the Department is hereby is of the Department): State Zip Alleghany	County	
2. The (a) address of this corporation's current registered off commercial registered office provider and the county of vicorrect the following information to conform to the record (a) Number and Street City (b) Name of Commercial Registered Office Provider c/o CT Corporation System 3. The statute by or under which it was incorporated: Section 4. The date of its incorporation: 12/18/78	Alleghany	County County	

Printer management of the Control

5903 DEC 18 611 #: #3

DSCB:15-1915/5915-2

6. Check one of the following:		
The amendment was adopted by the shareholders or members pursuant to 15 Pa.C.S. § 1914(a) and (b) or § 5914(a).		
The amendment was adopted by the board of direc	stors pursuant to 15 Ps. C.S. § 1914(c) or § 5914(b).	
7. Check, and if appropriate, complete one of the follow	wing:	
The amendment adopted by the corporation, set for	rth in full, is as follows	
That Article 1. of the Certificate of Incorporation of thi	s Corporation be amended to read in its entirety as follows:	
1. The same of the corporation is: Ortho-McNeil-Janz	sen Phermeceuticals, Inc.	
The amendment adopted by the corporation is set forth in full in Exhibit A attached heroto and made a part heroof.		
8. Check if the amendment restates the Articles: The restated Articles of Incorporation supersede the original articles and all amendments thereto.		
	IN TESTIMONY WHEREOF, the undersigned corporation has caused these Articles of Amendment to be eigned by a duly authorized officer thereof this	
	James Pharmaceutica Inc. Name of Corporation Signature Eric B. Jung, Vice President Title	

Delaware

PAGE 1

The First State

I; HARRIET SMITH WINDSOR, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF MERGER, WHICH MERGES:

"JANSSEN INC.", A DELAWARE CORPORATION,

"MCNEIL NEWCO, INC.", A DELAWARE CORPORATION,

WITH AND INTO "ORTHO-MCNEIL PHARMACEUTICAL, INC." UNDER THE NAME OF "ORTHO-MCNEIL PHARMACEUTICAL, INC.", A CORPORATION ORGANIZED AND EXISTING UNDER THE LAWS OF THE STATE OF PENNSYLVANIA, AS RECEIVED AND FILED IN THIS OFFICE THE TWENTY-FIRST DAY OF DECEMBER, A.D. 2007, AT 9:54 O'CLOCK P.M.

AND I DO HEREBY FURTHER CERTIFY THAT THE EFFECTIVE DATE OF THE AFORESAID CERTIFICATE OF MERGER IS THE THIRTY-FIRST DAY OF DECEMBER, A.D. 2007.

A FILED COPY OF THIS CERTIFICATE HAS BEEN FORWARDED TO THE NEW CASTLE COUNTY RECORDER OF DEEDS.

4479427 8100M

071357631

You may varify this cartificate online at corp.delaware.gov/authver.shtml

Darriet Smila Hindron

Harriet Smith Windsor, Secretary of State

AUTHENTICATION: 6267570

DATE: 12-27-07

State of Dalaware Secretary of State Division of Corporations Delivered 10:10 PM 12/21/2007 FILED 09:54 PM 12/21/2007 SRV 071357631 - 2571602 FILE

STATE OF DELAWARE CERTIFICATE OF MERGER DOMESTIC CORPORATION INTO FOREIGN CORPORATION

Pursuant to Title 8, Section 252 of the Delaware General Corporation Law, the undersigned corporation executed the following Certificate of Merger:

FIRST: The name and state of incorporation of each of the constituent corporations to the merger (the "Constituent Corporations") are as follows:

Name

State of Incorporation

Janssen Inc.

Delaware

McNeil Newco, Inc.

Delaware

Ortho-McNeil-Janssen

Pennsylvania

Pharmaceuticals, Inc.

SECOND: The Agreement and Plan of Merger has been approved, adopted, certified, executed and acknowledged by each of the constituent corporations pursuant to Title 8, Section 252.

THIRD: The name of the surviving corporation is Ortho-McNeil-Janssen Pharmaceuticals, Inc., a Pennsylvania corporation.

FOURTH: The Certificate of Incorporation of the surviving corporation shall be its Certificate of Incorporation.

FIFTH: The merger is to become effective on December 31, 2007.

SIXTH: The Agreement and Plan of Merger is on file at 1125 Trenton Harbourton Road, Titisville, New Jersey, 08560.

SEVENTH: A copy of the Agreement and Plan of Merger will be furnished by the surviving corporation on request, without cost, to any stockholder of the constituent corporations.

EIGHTH: The surviving corporation agrees that it may be served with process in the State of Delaware in any proceeding for enforcement of any obligation of the surviving corporation arising from this merger, including any suit or other proceeding to enforce the rights of any stockholders as determined in appraisal proceedings pursuant to the provisions of Section 262 of the Delaware General

Corporation laws, and irrevocably appoints the Secretary of State of Delaware as its agent to accept service of process in any such suit or proceeding. The Secretary of State shall mail any such process to the surviving corporation at 1125 Trenton Harbourton Road, Titusville, New Jersey 08560.

IN WITNESS WHEREOF, said surviving corporation has caused this certificate to be signed by its authorized officer, the 19^{12} day of December, 2007.

Authorized Officer

Name: James R. Hilton

Title: Vice President



United States Patent and Trademark Office

Home | Site Index | Search | Guides | Contacts | eBusiness | eBiz alerts | News |



Electronic Patent Assignment System

Confirmation Receipt

Your assignment has been received by the USPTO. The coversheet of the assignment is displayed below:

PATENT ASSIGNMENT

Electronic Version v1.1 Stylesheet Version v1.1

SUBMISSION TYPE:	NEW ASSIGNMENT
NATURE OF CONVEYANCE:	MERGER
EFFECTIVE DATE:	12/31/2007

CONVEYING PARTY DATA

Name	Execution Date
Janssen, Inc. the Limited Partner of Janssen, L.P.	12/31/2007

RECEIVING PARTY DATA

Name:	Ortho-McNeil-Janssen Pharmaceuticals, Inc.	
Street Address:	1125 Trenton-Harbourton Road	
City:	Titusville	
State/Country:	NEW JERSEY	
Postal Code:	08560	

PROPERTY NUMBERS Total: 1

Property Type	Number
Patent Number:	5158952

CORRESPONDENCE DATA

Fax Number:

(732)524-2808

Correspondence will be sent via US Mail when the fax attempt is unsuccessful. Phone:

Email:

7816747816

Correspondent Name:

JNJUSPATENT@CORUS.JNJ.COM

Philip S. Johnson

Address Line 1: One Johnson & Johnson Plaza Address Line 2: Johnson & Johnson Address Line 4: New Brunswick, NEW JERSEY 08933		
ATTORNEY DOCKET NUMBER:	JAB0650USA	
NAME OF SUBMITTER: Kristin Mele		
Signature:	/Kristin Miele/	
Date:	05/20/2009	
Total Attachments: 8 source=Merger Docs for 3542a#page1.tif source=Merger Docs for 3542a#page2.tif source=Merger Docs for 3542a#page3.tif source=Merger Docs for 3542a#page4.tif source=Merger Docs for 3542a#page5.tif source=Merger Docs for 3542a#page6.tif source=Merger Docs for 3542a#page7.tif source=Merger Docs for 3542a#page7.tif source=Merger Docs for 3542a#page8.tif		
RECEIPT INFORMATION		
EPAS ID: PAT88261 Receipt Date: 05/20/2000 Fee Amount: \$40	The state of the s	

Return to home page Start another assignment from the same template

| HOME | INDEX | SEARCH | BUSINESS | CONTACT US | PRIVACY STATEMENT



US005254556A

United States Patent [19] Patent Number: Janssen et al.

Date of Patent: [45]

* Oct. 19, 1993

[54]	54] 3-PIPERIDINYL-1,2-BENZISOXAZOLES		[52] U.S. Cl 514/258; 544/282	
[75]	Inventors: Cornelus G. M. Janssen, Vosselaar;		[58] Field of Search 544/282; 514/258	
	Alfonsus G. Knaeps, Herentals; Ludo E. J. Kennis, Turnhout; Jan Vandenberk, Beerse, all of Belgium	[56] References Cited		
		U.S. PATENT DOCUMENTS		
[73]	Assignee:	Janssen Pharmaceutica N.V., Beerse, Belgium	4,804,663 2/1989 Kennis 544/282 5,151,424 9/1992 Janssens 544/282 5,158,952 10/1992 Janssen 544/282	
[*]	Notice:	The portion of the term of this patent subsequent to Oct. 27, 2009 has been disclaimed.	Primary Examiner—Mark L. Berch Attorney, Agent, or Firm—Charles J. Metz	
[21]	Appl. No.:	932,142	[57] ABSTRACT	
[22]	Filed:	Aug. 19, 1992	The invention relates to C ₂₋₂₀ alkanoic acid esters 3-[2-[4-(6-fluoro-1,2-benzisoxazol-3-yl)-1-piperidinyl]e	
	Related U.S. Application Data (60) Division of Ser. No. 422,847, Oct. 17, 1989, Pat. No. 5,158,952, which is a continuation-in-part of Ser. No. 267,852, Nov. 2, 1989, abandand of the continuation of Ser. No. 267,852, Nov. 2, 1989, abandand of the continuation of Ser. No. 267,852, Nov. 2, 1989, abandand of Ser. No. 267,852, Nov. 267,852		thyl]-6, 7,8,9-tetrahydro-9-hydroxy-2 -methyl-4H-	
[60]			able acid addition salts thereof, and enantiomeric forms thereof, which are useful in the treatment of warm-blooded animals suffering from psychotic diseases.	
[51]	Int. C3.5	COTD 487 /04: COTD 412 /04.	orocaea ammais surreting from psychotic diseases.	

A61K 31/505

6 Claims, No Drawings

,

3-PIPERIDINYL-1,2-BENZISOXAZOLES

This application is a division of our copending application Ser. No. 422,847, filed Oct. 17, 1989, now U.S. 5 Pat. No. [5,158,952], which in turn was a continuation-in-part of application Ser. No. 267,857, filed Nov. 7, 1988, now abandoned.

BACKGROUND OF THE INVENTION

In EP-A-0,196,132 there are described a number of 3-piperidinyl-1,2-benzisoxazoles having antipsychotic activity.

The compounds of the present invention differ therefrom by the specific substitution on the (2-C₁₋₄alkyl-6,7,8,9-tetrahydro-4-0xo-4<u>H</u>-pyrido[1,2-a]-pyrimidin-3-yl)alkyl substituent at the 1 position of the piperidinyl moiety.

DESCRIPTION OF THE INVENTION

The present invention is concerned with novel 3piperidinyl-1,2-benzisoxazoles having the formula

the pharmaceutically acceptable acid addition salts 35 R thereof, and the stereochemically isomeric forms thereof, wherein

Alk is C1-4alkanediyl;

R1 is hydrogen, C1-4alkyl or halo;

R2 is C1-4alkyl;

R3 is hydroxy or R4-C(=O)O-; and

R4 is C1-19alkyl.

In the foregoing definitions C1-4alkanediyl defines bivalent straight and branch chained alkanediyl radicals having from 1 to 4 carbon atoms such as, for example, methylene, 1,2-ethanediyl, 1,3-propanediyl, 1,4butanediyl and the branched isomers thereof; C1-4alkyl defines straight and branch chained saturated hydrocarbon radicals having from 1 to 4 carbon atoms such as, for example, methyl, ethyl, propyl, 1-methylethyl, butyl, 1-methylpropyl, 2-methylpropyl and 1,1-dimethylethyl; C1-19alkyl defines C1-4alkyl radicals as defined hereinabove and the higher homologs thereof having from 5 to 19 carbon atoms such as, for example, pentyl, 55 hexyl, heptyl, octyl, nonyl, decyl, undecyl, dodecyl, tridecyl, tetradecyl, pentadecyl, hexadecyl, heptadecyl, octadecyl, nonadecyl and the like; halo is generic to fluoro, chloro, bromo and iodo. R3 as defined hereinabove may be substituted on any of the 6,7,8 or 9 posi- 60 of the 6,7,8,9-tetrahydro-2-C1-4alkyl-4Hpyrido[1,2-a]pyrimidin-4-one moiety.

Particular compounds are those compounds of formula (I) wherein R³ is substituted on the 9 position of the 6,7,8,9-tetrahydro-2-C₁₋₄alkyl-4<u>H</u>-pyrido[1,2-65 a]pyrimidin-4-one moiety.

More particular compounds within the invention are those particular compounds wherein Alk is ethanediyl; and/or R¹ is halo, in particular fluoro and more in particular 6-fluoro; and/or R² is methyl.

Among the above defined groups of compounds of formula (I) those compounds wherein R⁴ is C₇₋₁₃alkyl, in particular heptyl, nonyl, undecyl or tridecyl are of particular interest.

The most interesting compounds within the invention are selected from the group consisting of 3-[2-[4-(6-fluoro-1,2-benzisoxazol-3-yl)-1-piperidinyl]ethyl]-6,7,8,9-tetrahydro-9-hydroxy-2-methyl-4H-pyrido[1,2-a]pyrimidin-4-one, the pharmaceutically acceptable acid addition salt forms and the enantiomeric forms

From formula (I) it is evident that the compounds of this invention have at least one asymmetric carbon atom in their structure, namely the carbon atom bearing the R³ substituent. The absolute configuration of this centre may be indicated by the stereochemical descriptors R and S, this R and S notation corresponding to the rules described in Pure Appl. Chem. 1976, 45, 11-30. Unless otherwise mentioned or indicated, the chemical designation of compounds denotes the mixture of all possible stereochemically isomeric forms, said mixtures containing all diastereomers and enantiomers of the basic molecular structure. Sterochemically isomeric forms of the compounds of formula (I) are obviously intended to be embraced within the scope of the invention.

The compounds of formula (I) can generally be prepared by N-alkylating a 3-piperidinyl-1,2-benzisoxazole of formula (II) with an alkylating reagent of formula (III) following art-known N-alkylation procedures.

$$R^3$$
 N
 N
 $Alk-W$

40

In formula (III) W represents an appropriate reactive leaving group such as, for example, halo, e.g. chloro, bromo or iodo; sulfonyloxy, e.g. methanesulfonyloxy, trifluoromethanesulfonyloxy, benzenesulfonyloxy, 4methylbenzenesulfonyloxy and the like leaving groups. Said N-alkylation reaction can conveniently be carried out by mixing the reactants, optionally in a reactioninert solvent such as, for example, water, an aromatic solvent, e.g. benzene, methylbenzene, dimethylbenzene, chlorobenzene, methoxybenzene and the like; a C1-6alkanol, e.g. methanol, ethanol, 1-butanol and the like; a ketone, e.g. 2-propanone, 4-methyl-2-pentanone and the like; an ester, e.g. ethyl acetate, y-butyrolactone and the like; an ether, e.g. 1,1'-oxybisethane, tetrahydrofuran, 1,4-dioxane and the like; a dipolar aprotic solvent, e.g. N,N-dimethylformamide, N,N-dimethylacetamide, dimethylsulfoxide, pyridine, 1,3-dimethyl-3,4,5,6-tetrahydro-2(1H)-pyrimidinone, 1,3-dimethyl-2-imidazolidi-

none, 1,1,3,3-tetramethylurea, 1-methyl-2-pyrrolidinone, nitrobenzene, acetonitrile and the like; or a mixture of such solvents. The addition of an appropriate base such as, for example, an alkali metal or an earth alkaline metal carbonate, hydrogen carbonate, hydrox- 5 ide, oxide, carboxylate, alkoxide, hydride or amide, e.g. sodium carbonate, sodium hydrogen carbonate, potassium carbonate, sodium hydroxide, calcium oxide, sodium acetate, sodium methoxide, sodium hydride, sodium amide and the like, or an organic base such as, for 10 example, a tertiary amine, e.g. N,N-diethylethanamine, N-(1-methylethyl)-2-propanamine, 4-ethylmorpholine, 1,4-diazabicyclo[2,2,2]octane, pyridine and the like, may optionally be used to pick up the acid which is formed during the course of the reaction. In some in- 15 stances the addition of an iodide salt, preferably an alkali metal iodide, or a crown ether, e.g. 1,4,7,10,13,16hexaoxa-cyclooctadecane and the like, may be appropriate. Stirring and somewhat elevated temperatures may enhance the rate of the reaction; more in particular 20 the reaction may be conducted at the reflux temperature of the reaction mixture. Additionally, it may be advantageous to conduct said N-alkylation under an inert atmosphere such as, for example, oxygen-free argon or nitrogen gas.

Alternatively, said N-alkylation may be carried out by applying art-known conditions of phase transfer catalysis reactions. Said conditions comprise stirring the reactants, with an appropriate base and optionally under an inert atmosphere as defined hereinabove, in 30 the presence of a suitable phase transfer catalyst such as, for example, a trialkylphenylmethylammonium, tetraalkylammonium, tetraalkylammonium, tetraalkylammonium, tetraalkylammonium halide, hydroxide, hydrogen sulfate and the like catalysts. Somewhat elevated temperatures may 35 be appropriate to enhance the rate of the reaction.

In this and the following preparations, the reaction products may be isolated from the medium and, if necessary, further purified according to methodologies generally known in the art such as, for example, extraction, crystallization, trituration and chromatography.

The compounds of formula (I) can also be obtained by the cyclization of an oxime of formula (IV), wherein Y is a reactive leaving group such as, for example, halo or nitro. Preferably Y is a halo group and more particu- 45 larly fluoro.

Said cyclization reaction of the oxime of formula (IV) may conveniently be conducted by treatment with an appropriate base, preferably in a suitable reaction-inert 60 solvent at temperatures in the range of 20° to 200° C., preferably at 50° to 150° C., and in particular at the reflux temperature of the reaction mixture. Or, if desirable, said base may first be added, preferably at room temperature, whereupon the thus formed oxime salt is 65 cyclized, preferably at an increased temperature and more preferably at the reflux temperature of the reaction mixture. Appropriate bases for said cyclization are,

for example, alkali and earth alkaline metal carbonates, hydrogen carbonates, hydroxides, alkoxides or hydrides, e.g. sodium carbonate, sodium hydrogen carbonate, potassium carbonate, sodium hydroxide, sodium methoxide, sodium hydride or organic bases such as amines, e.g. N,N-diethylethanamine, 4-ethylmorpholine and the like bases. Suitable solvents are, for example, water; aromatic hydrocarbons, e.g. benzene, methylbenzene, dimethylbenzene and the like; halogenated hydrocarbons, e.g. dichloromethane, trichloromethane, 1,2-dichloroethane and the like; lower alkanols, e.g. methanol, ethanol, 1-butanol and the like; ketones, e.g. 2-propanone, 4-methyl-2-pentanone and the like; ethers, e.g. 1,4-dioxane, tetrahydrofuran and the like; dipolar aprotic solvents, e.g. N,N-dimethylformamide, N,Ndimethylacetamide, dimethylsulfoxide, 1-methyl-2-pyrrolidinone and the like, or mixtures of such solvents.

The compounds of formula (I) can also be obtained by cyclizing an activated oxime derivative of formula

wherein L is an acid residue and more particularly is formyl, (C1-6alkyl or aryl)-carbonyl, e.g. acetyl, propionyl, benzoyl and the like; (C1.6alkyl or aryl)oxycarbonyl, e.g. methoxycarbonyl, ethoxycarbonyl, (1,1-dimethyl)ethoxycarbonyl, phenyloxycarbonyl and the like; (C1.6alkyl or aryl)sulfonyl, e.g. methanesulfonyl, benzenesulfonyl, 4-methylbenzenesulfonyl, 2-naphthalenesulfonyl and the like; N-acylaminocarbonyl, e.g. trichloromethylcarbonylaminocarbonyl and the like. Said cyclization reaction of the activated oxime derivative of formula (V) may conveniently be conducted by treatment with an appropriate base, preferably in a suitable reaction-inert solvent, at temperatures in the range from 20° to 200° C., particularly from 50° to 150° C. and preferably at the reflux temperature of the reaction mixture. In some instances however, it may be advanta-

geous not to add a base to the reaction mixture and to remove the acid liberated during the reaction by destillation at normal pressure or, if desired, at reduced pressure. Alternatively, said cyclization may also be effected by heating the oxime derivative (V) in vacuo without a solvent. Appropriate bases are for example, alkali and earth alkaline metal carbonates, hydrogen carbonates and organic amines, e.g. sodium carbonate, potassium carbonate, sodium hydrogen carbonate, N,N-

diethylethanamine, 4-ethylmorpholine, 1,4-diazabicyclo[2.2.2]octane, pyridine and the like bases. Suitable solvents for said cyclization are, for example, aromatic hydrocarbons, e.g. benzene, methylbenzene, dimethylbenzene and the like; ethers, e.g. 1,1'-oxybisethane, 5 1,1'-oxybisbutane, tetrahydrofuran, 1,4-dioxane, 1,1'oxybis[2-methoxyethane], 2,5,8,11-tetraoxadodecane and the like; dipolar aprotic solvents, e.g. N,N-dimethylformamide, N,N-dimethylacetamide, 1-methyl-2pyrrolidinone, hexamethylphosphoric triamide, pyri- 10 dine, acetic anhydride and the like; halogenated hydrocarbons, e.g. trichloromethane, tetrachloromethane, 1,2-dichloroethane, chlorobenzene and the like solvents.

The compounds of formula (I) wherein R³ is R⁴—(C- 15 =O)-O-, said compounds being represented by formula (I-b), can be obtained by the O-acylation reaction of a compound of formula (I-a) wherein R3 is hydroxy, with a carboxylic acid of formula (VI) or a suitable reactive functional derivative thereof such as, for exam- 20 ple, an acyl halide, symmetric or mixed anhydride, ester or amide, acyl azide and the like derivatives. Said functional derivatives may be prepared following art-known methods, for example, by reacting the carboxylic acid of formula (VI) with a halogenating reagent such as, for 25 example, thionyl chloride, phosphorous trichloride, phosphoryl chloride, oxalyl chloride and the like, or by reacting said carboxylic acid (VI) with an acyl halide such as acetyl chloride and the like. Said derivatives may be generated in situ, or if desired, be isolated and 30 ing pyrimidin-4-ones such as, for example, by reacting further purified before reacting them with the compound of formula (I-a).

6 pyridinium iodide, phosphorus pentoxide, 1,1'-carbonylbis[1H-imidazole], 1,1'-sulfonyl bis[1H-imidazole] and the like reagents.

Said O-acylation reactions can conveniently be carried out by stirring the reactants optionally in a suitable reaction-inert solvent such as, for example, a halogenated hydrocarbon, e.g. dichloromethane, trichloromethane and the like; an aromatic hydrocarbon, e.g. benzene, methylbenzene and the like; an ether, e.g. 1,1'-oxybisethane, tetrahydrofuran and the like; or a dipolar aprotic solvent, e.g. N,N-dimethylformamide, N,N-dimethylacetamide, or pyridine and the like. In some instances it may be appropriate to employ an excess of one of the reagents as solvent. The water, acid. alcohol or amine which is liberated during the course of the reaction may be removed from the reaction mixture by art-known procedures such as, for example, azeotropical destillation, complexation, salt formation and the like methods. In some instances particularly the addition of a suitable base such as, for example, a tertiary amine, e.g. N,N-diethyl-ethanamine, 4-ethylmorpholine, pyridine or N,N-dimethyl-4-aminopyridine, may be appropriate. Further, in order to enhance the rate of the reaction, said acylation reaction may advantageously be conducted at a somewhat elevated temperature, and in particular instances at the reflux temperature of the reaction mixture.

The compounds of formula (I) can also be prepared following art-known cyclization procedures for preparan amidine of formula (VII) with a β -dicarbonyl intermediate of formula (VIII), or by cyclizing a reagent of

HO

N

R

Alk-N

O

R4-(C=0)-OH (VI)

O-acylation reaction

N

R

R

Alk-N

N

O

(I-a)

N

O

(I-b)

O

$$R^4$$
-(C=0)-OH (VI)

O-acylation reaction

N

O

 R^2

(I-b)

Alternatively, the compound of formula (I-a) and the carboxylic acid of formula (VI) may also be esterified in 65 lae (VIII), (IX) and (X) R5 represents an appropriate the presence of a suitable reagent capable of forming esters such as, for example, a dehydrating reagent, e.g. dicyclohexylcarbodiimide, 2-chloro-1-methyl-

formula (IX) with an enamine of formula (X). In formuleaving group such as, for example, C1-6alkyloxy, hydroxy, halo, amino, mono- or di-(C1-6alkyl)amino and the like.

25

30

Said cyclization reactions may generally be carried out by stirring the reactants, optionally in the presence of a suitable reaction-inert solvent such as, for example, 35 an aliphatic, alicyclic or aromatic hydrocarbon, e.g. hexane, cyclohexane, benzene and the like; pyridine, N,N-dimethylformamide and the like dipolar aprotic solvents. In order to enhance the rate of the reaction it may be appropriate to increase the temperature, more 40 can be obtained by converting the racemic mixtures of particularly, it may be recommendable to carry out the reaction at the reflux temperature of the reaction mix-

The compounds of formula (I) have basic properties and, consequently, they may be converted to their ther- 45 apeutically active non-toxic acid addition salt forms by treatment with appropriate acids, such as, for example, inorganic acids, such as hydrohalic acid, e.g. hydrochloric, hydrobromic acid and the like, sulfuric acid, nitric acid, phosphoric acid and the like; or organic 50 acids, such as, for example, acetic, propanoic, hydroxyacetic, 2-hydroxypropanoic, 2-oxopropanoic, ethanedioic, propanedioic, butanedioic, (Z)-2-butenedioic, (E)-2-butenedioic, 2-hydroxybutanedioic, 2,3-dihydroxvbutanedioic. 2-hydroxy-1,2,3-propanetricarboxylic, 55 methanesulfonic, ethanesulfonic, benzenesulfonic, 4methylbenzenesulfonic, cyclohexanesulfamic, hydroxybenzoic, 4-amino-2-hydroxybenzoic and the like acids. Conversely the salt form can be converted into the free base form by treatment with alkali.

The term acid addition salt as used hereinabove also comprises the solvates which the compounds of formula (I) are able to form and said solvates are meant to be included within the scope of the present invention. Examples of such solvates are e.g., the hydrates, alcoho- 65 lates and the like.

Enantiomeric forms of the compounds of formula

HO
$$\stackrel{N}{\underset{0}{\longleftarrow}}$$
 $\stackrel{N}{\underset{N}{\longleftarrow}}$ $\stackrel{R^2}{\underset{N}{\longleftarrow}}$ $\stackrel{N}{\underset{N}{\longleftarrow}}$ $\stackrel{O}{\underset{R^1}{\longleftarrow}}$

the compounds of formula (I-a) with a suitable resolving reagent such as, for example, a chiral acid, e.g. tartaric, malic and mandelic acids, campher sulfonic acid, 4,5-dihydro-1H-2-benzopyran-2-carboxylic acid and the like, or the reactive functional derivatives thereof, e.g. the acyl halides, to a mixture of diastereomeric salts or compounds, particularly esters; physically separating said mixtures of diastereomeric salts or compounds by, for example, selective crystallization or chromatographic techniques, e.g. liquid chromatography and the like methods; and finally converting said separated diastereomeric salts or compounds into the corresponding enantiomeric forms of the compounds of formula (I-a) by hydrolysis in an acidic or basic aqueous medium, optionally at an elevated temperature.

Some of the intermediates and starting materials for use in the foregoing preparations are known compounds, while others are novel. The intermediates of formula (II) and methods of preparing them are known from EP-A-0,196,132. The alkylating reagents of formula (III) are novel and can be prepared according to art-known methodologies of preparing similar compounds and will be described hereinafter in more detail.

By condensing an optionally protected 2-aminopyridine derivative (XI) with an α -acyl lactone (XII) in the presence of an activating reagent in a suitable reactioninert solvent, an intermediate of formula (XIII) can be obtained.

$$P = O + N + R^{2} + R^{2}$$

$$O + R^{2}$$

In the formulae (XI), (XIII) and hereinafter whenever it 25 pounds of formula (I-a). occurs, P represents hydrogen or a protective group which can be readily removed such as, for example, a hydrogenolyzable group, e.g. phenylmethyl and the like; a hydrolyzable group, e.g. methyl and the like. 30 Appropriate activating reagents for said condensation reaction typically are halogenating reagents such as, for example, phosphoryl chloride, phosphoryl bromide, phosphorous trichloride, thionyl chloride and the like

The subsequent catalytic hydrogenation of intermediate (XIII) in a suitable reaction-inert solvent in the presence of hydrogen, optionally at an elevated temperature and/or pressure, with a catalyst such as, for example, 40 palladium-on-charcoal and the like, can yield a protected intermediate (XIV) in case P is an alkyl group such as, for example, methyl;

$$P-O \xrightarrow{N} \underset{O}{\underset{\parallel}{N}} R^2 ; \qquad (XIV)$$

or, on the other hand, when P is hydrogen or a hydrogenolyzable group such as, for example, phenylmethyl, an alkylating reagent of formula (III-a) wherein 55 R3 is hydroxy can be obtained directly.

HO
$$\stackrel{N}{\underset{\parallel}{\bigcup}}$$
 $\stackrel{R^2}{\underset{\wedge}{\bigvee}}$ $\stackrel{\text{(II-a)}}{\underset{\wedge}{\bigvee}}$ 6

Suitable solvents for said catalytic hydrogenation reaction comprise water; C1-4alkanols, e.g. methanol, ethanol, 2-propanol and the like; ethers, e.g. 1,1'-oxybise-

thane, 1,4-dioxane, tetrahydrofuran, 2-methoxyethanol and the like; halogenated hydrocarbons, e.g. trichloromethane and the like; dipolar aprotic solvents, e.g. N,Ndimethylformamide and the like; esters, e.g. ethyl acetate, butyl acetate and the like; or a mixture of such solvents.

The intermediate (XIV) wherein P represents an alkyl group may be deprotected to a reagent of formula (III-a) by heating the former with concentrated hydrobromic or hydroiodic acid or by reaction with Lewis acids such as, for example, boron trihalides, e.g. boron trifluoride, boron trichloride and in particular boron tribromide; iodotrimethylsilane; or aluminum chloride and the like Lewis acids.

The intermediate of formula (III-a) may be Oacylated with a carboxylic acid of formula (VI) or a functional derivative thereof as defined hereinabove, to an alkylating reagent of formula (III-b) wherein R3 is R4-C(=0)-O- following the same procedures as described hereinabove for the O-acylation of the com-

The intermediates of formula (IV) may be prepared by N-alkylating a reagent of formula (III) with an oxime derivative of formula (XV) following the same procedures as described hereinabove for the preparation of the compounds of formula (I) from the intermediates (II) and (III). The derivatives (XV) are known from EP-A-0,196,132.

$$\begin{array}{c|c}
R^3 & & & \\
& & & \\
N & & \\
N$$

HN
$$NOH$$
 N -alkylation $reaction$ (IV)

The intermediates of formula (V) may be obtained by reacting an oxime of formula (XVI) with an activated acid derivative of formula L-W1 (XVII).

$$R^{2}$$
NOH
OH
 (XVI)
 (XVI)

wherein L is an acid residue as defined hereinabove and W1 represents a reactive leaving group such as, for example, halo, (aryl or C1.6alkyl)carbonyloxy, (aryl or C1-6alkyi)oxy and the like. As typical examples of the reagent of formula (XVII) there may be mentioned carboxylic acid anhydrides, e.g. acetic anhydride, benzoic anhydride and the like; carboxylic acid halides, e.g. acetyl chloride, benzoyl chloride and the like; carbono- 20 chloridates, e.g. methyl, ethyl or phenyl carbonochloridate and the like; di(C1.6alkyl)carbonates, e.g. dimethylcarbonate, diethylcarbonate and the like. The reaction of the intermediates (XVI) with the activated acid derivatives (XVII) may be carried out following art- 25 known esterification procedures, e.g. by stirring the reactants at a somewhat elevated temperature, preferably in a reaction-inert solvent such as, for example, an aromatic hydrocarbon, e.g. benzene, methylbenzene and the like; a halogenated hydrocarbon, e.g. dichloro- 30 methane, trichloromethane and the like; a ketone, e.g. 2-propanone, 4-methyl-2-pentanone and the like; an ether, e.g. 1,1'-oxybisethane, 1,4-dioxane and the like, a dipolar aprotic solvent, e.g. N,N-dimethylformamide, pyridine and the like solvents. In some instances it may 35 be appropriate to add a suitable base such as, for example, N.N-diethylethanamine, N-(1-methylethyl)-2propanamine, 4-ethylmorpholine, N,N-dimethyl-4aminopyridine and the like bases to the reaction mixture.

The intermediate of formula (XVI) in turn may be prepared by N-alkylating a reagent of formula (III) with an oxime derivative of formula (XVIII)

following the same procedures as described hereinabove for the preparation of the compounds of formula (I) from the intermediates (II) and (III).

The compounds of formula (I) and some of the inter-65 mediates in the present invention contain at least one asymmetric carbon atom. Pure stereochemically isomeric forms of said compounds and said intermediates

can be obtained by the application of art-known procedures. For example, diastereoisomers can be separated by physical methods such as selective crystallization or chromatographic techniques, e.g. counter current distribution, liquid chromatography and the like methods. Enantiomers can be obtained from racemic mixtures by first converting said racemic mixtures with suitable resolving agents such as, for example, chiral acids, to mixtures of diastereomeric salts or compounds; then physically separating said mixtures of diastereomeric salts or compounds by, for example, selective crystallization or chromatographic techniques, e.g. liquid chromatography and the like methods; and finally converting said separated diastereomeric salts or compounds into the corresponding enantiomers.

Pure stereochemically isomeric forms of the compounds of formula (I) may also be obtained from the pure stereochemically forms of the appropriate intermediates and starting materials, provided that the intervening reactions occur stereospecifically. The pure and mixed stereochemically isomeric forms of the compounds of formula (I) are intended to be embraced within the scope of the present invention.

The compounds of formula (I), the pharmaceutically acceptable acid addition salts and stereochemically isomeric forms thereof, are potent antagonists of neuro-40 transmitters and in particular of the mediators serotonin and dopamine. Antagonizing said mediators will suppress or relieve a variety of symptoms associated with phenomena induced by the release, in particular the excessive release, of these mediators. Therapeutic indi-45 cations for using the present compounds are mainly in the CNS area, the gastrointestinal and cardiovascular field and related domains. The compounds of formula (I) are particularly useful as antipsychotic agents. Serotonin antagonists are reportedly effective in combatting psychoses, aggressive behaviour, anxiety, depression and migraine. Dopamine receptor antagonists are known to have neuroleptic properties. Combined serotonin-dopamine antagonists are especially interesting as they appear to offer relief of both the positive and 55 negative symptoms of schizophrenia. Further the present compounds also appear to be useful therapeutic agents for combatting autism. Therapeutic applications in the gastrointestinal field comprise their use as, for instance, anti-diarrhoeals, inhibitors of gastro-oeso-60 phageal reflux and particularly antiemetics, e.g. in cancer patients receiving chemotherapy and radiation treatment. Further, serotonin is a potent broncho- and vasoconstrictor and thus the present antagonists may be used against hypertension and vascular disorders. In addition, serotonin antagonists have been associated with a number of other properties such as, the suppression of appetite and promotion of weight loss, which may prove effective in combating obesity; and also the

14

alleviation of withdrawal symptoms in addicts trying to discontinue drinking and smoking habits.

The compounds of formula (I) show the additional advantage of being eliminated rather slowly from the body and thus of being long acting. This can be evidenced, for example, by measuring the plasma levels after oral administration to dogs and by the long acting antiemetic effect exerted by the present compounds on dogs challenged with the dopamine agonist apomorphine. Especially the compounds of formula (I) wherein 10 R3 is a higher alkylcarbonyloxy radical have a long duration of action. Hence, the compounds of formula (I) only need to be administered at relatively large intervals, e.g. several days or weeks, the actual time of administration depending on the nature of the compound 15 of formula (I) used and the condition of the subject to be treated. Consequently, the present compounds allow for a more efficient therapy: the slow elimination facilitates maintaining a stable plasma concentration at a non-toxic, effective level and the reduction in the num- 20 ber of administrations may be expected to result in better compliance of the subject to be treated with the prescribed medication.

In view of their useful pharmacological properties, the subject compounds may be formulated into various 25 pharmaceutical forms for administration purposes. To prepare the pharmaceutical compositions of this invention, an effective amount of the particular compound, in acid addition salt or base form, as the active ingredient is combined in intimate admixture with a pharmaceuti- 30 cally acceptable carrier, which may take a wide variety of forms depending on the form of preparation desired for administration. These pharmaceutical compositions are desirably in unitary dosage form suitable, preferably, for administration orally, rectally, percutaneously, 35 or by parenteral injection. For example, in preparing the compositions in oral dosage form, any of the usual pharmaceutical media may be employed, such as, for example, water, glycols, oils, alcohols and the like in the case of oral liquid preparations such as suspensions, 40 syrups, elixirs and solutions; or solid carriers such as starches, sugars, kaolin, lubricants, binders, disintegrating agents and the like in the case of powders, pills. capsules and tablets. Because of their ease in administration, tablets and capsules represent the most advanta- 45 geous oral dosage unit form, in which case solid pharmaceutical carriers are obviously employed. For parenteral compositions, the carrier will usually comprise sterile water, at least in large part, though other ingredients, for example, to aid solubility, may be included. 50 Injectable solutions, for example, may be prepared in which the carrier comprises saline solution, glucose solution or a mixture of saline and glucose solution. Injectable solutions containing compounds of formula in an oil for prolonged action. Appropriate oils for this purpose are, for example, peanut oil, sesame oil, cottonseed oil, corn oil, soy bean oil, synthetic glycerol esters of long chain fatty acids and mixtures of these and other oils. Injectable suspensions may also be prepared in 60 which case appropriate liquid carriers, suspending agents and the like may be employed. In the compositions suitable for percutaneous administration, the carrier optionally comprises a penetration enhancing agent and/or a suitable wettable agent, optionally combined 65 with suitable additives of any nature in minor proportions, which additives do not cause any significant deleterious effects on the skin. Said additives may facilitate

the administration to the skin and/or may be helpful for preparing the desired compositions. These compositions may be administered in various ways, e.g., as a transdermal patch, as a spot-on or as an ointment. Acid addition salts of (I) due to their increased water solubility over the corresponding base form, are obviously more suitable in the preparation of aqueous compositions.

It is especially advantageous to formulate the aforementioned pharmaceutical compositions in dosage unit form for ease of administration and uniformity of dosage. Dosage unit form as used in the specification and claims herein refers to physically discrete units suitable as unitary dosages, each unit containing a predetermined quantity of active ingredient calculated to produce the desired therapeutic effect, in association with the required pharmaceutical carrier. Examples of such dosage of unit forms are tablets (including scored or coated tablets), capsules, pills, powder packets, wafers, injectable solutions or suspensions, teaspoonfuls, tablespoonfuls and the like, and segregated multiples thereof.

In view of the usefulness of the subject compounds in the treatment of diseases associated with the release of neurotransmitters, in particular in the treatment of psychotic diseases, it is evident that the present invention provides a method of treating warm-blooded animals suffering from such diseases, in particular psychotic diseases, said method comprising the systemic administration of an antipsychotic amount of a compound of formula (I) or a pharmaceutically acceptable acid addition salt thereof, effective in treating diseases associated with the release of neurotransmitters, in particular psychotic diseases. Those of skill in the treatment of such diseases could easily determine the effective amount from the test results presented hereinafter. In general it is contemplated that an effective antipsychotic amount would be from about 0.01 mg/kg to about 4 mg/kg body weight, more preferably from about 0.04 mg/kg to about 2 mg/kg body weight.

The following examples are intended to illustrate and not to limit the scope of the present invention. Unless otherwise stated all parts therein are by weight.

EXPERIMENTAL PART

A. Preparation of Intermediates

EXAMPLE 1

a) To a stirred mixture of 84 parts of phosphoryl chloride and 540 parts of methylbenzene were added 20 parts of 3-(phenylmethoxy)-2-pyridinamine. The mixture was stirred at 50° C. and 22 parts of 3-acetyl-4,5dihydro-2(3H)-furanone were added. The reaction mixture was stirred for 5 hours at 90° C. Another portion of 22 parts of 3-acetyl-4,5-dihydro-2(3H)-furanone was (1) wherein R³ is R⁴—C(=0)—O— may be formulated 55 added and stirring was continued for 30 minutes at 90° C. The solution was allowed to stand overnight at 90° C. The whole was poured into crushed ice and treated with an ammonium hydroxide solution 25%. The product was extracted with trichloromethane. The extract was dried, filtered and evaporated. The residue was purified by column chromatography over silica gel using a mixture of trichloromethane and methanol (98:2 by volume) as eluent. The pure fractions were collected and the eluent was evaporated. The residue was stirred in 2-propanol. The product was filtered off, washed with a mixture of 2-propanol and 1,1'-oxybisethane and dried at 50° C., yielding 20.5 parts (62.3%) of 3-(2chloroethyl)-2-methyl-9-(phenylmethoxy)-4H-

pyrido[1,2-a]pyrimidin-4-one; mp. 141.1° C. (intermediate 1)

b) A mixture of 3.3 parts of 3-(2-chloroethyl)-2-methyl-9-(phenylmethoxy)-4H-pyrido[1,2-a]pyrimidin-4-one and 120 parts of methanol was hydrogenated at normal pressure and at room temperature with 2.0 parts of palladium-on-charcoal catalyst 10%. After the calculated amount of hydrogen was taken up, the catalyst was filtered off and the filtrate was evaporated to dry, yielding 2.4 parts (99%) of 3-(2-chloroethyl)-6,7,8,9-tet- 10 rahydro-9-hydroxy-2-methyl-4H-pyrido[1,2-a]pyrimidin-4-one as an oily residue. (intermediate 2)

EXAMPLE 2

a) A mixture of 17 parts of 5-methoxy-2-pyridina- 15 mine, 61 parts of phosphoryl chloride and 348 parts of methylbenzene was stirred for 2 hours at 60° C. 18 Parts of 3-acetyl-4,5-dihydro-2(3H)-furanone were added and the reaction mixture was stirred overnight at 90° C. The whole was poured into crushed ice and treated with 20 ammonium hydroxide. The product was extracted with trichloromethane. The extract was dried, filtered and evaporated. The residue was stirred in a mixture of hexane and ethyl acetate (50:50 by volume). The precipitated product was filtered off and dried, yielding 10 25 parts (30.4%) of 3-(2-chloroethyl)-7-methoxy-2-methyl-4H-pyrido-[1,2-a]pyrimidin-4-one; mp. 150° C. (inter-

b) A mixture of 10 parts of 3-(2-chloroethyl)-7methoxy-2-methyl-4H-pyrido[1,2-a]pyrimidin-4-one, 40 30 parts of 2-propanol saturated with hydrogen chloride and 160 parts of methanol was hydrogenated at normal pressure and at room temperature with 2.0 parts of palladium-on-charcoal catalyst 10%. After the calculated amount of hydrogen was taken up, the catalyst 15 was filtered off over diatomaceous earth and the filtrate was evaporated. The oily residue was taken up in 80 parts of 2-propanol and 2,2'-oxybispropane. After stirring overnight at room temperature, the precipitated product was filtered off, washed with a mixture of 2propanol and 2,2'-oxybispropane and dried in vacuo at 50° C., yielding 7.5 parts (64.0%) of 3-(2-chloroethyl)-6,7,8,9-tetrahydro-7-methoxy-2-methyl-4H-pyrido[1,2a]pyrimidin-4-one monohydrochloride; mp. 170" C. (intermediate 4)

c) A mixture of 6 parts of 3-(2-chloroethyl)-6,7,8,9tetrahydro-7-methoxy-2-methyl-4H-pyrido[1,2a]pyrimidin-4-one, 4:8 parts of 6-fluoro-3-(4piperidinyl)-1,2-benzisoxazole monohydrochloride, 6.1 of methanol was stirred overnight at reflux temperature. The reaction mixture was evaporated and the residue was taken up in water. The product was extracted with trichloromethane. The extract was dried, filtered and evaporated. The residue was purified by 55 column chromatography over silica gel using a mixture of trichloromethane and methanol (95:5 by volume) as eluent. The pure fractions were collected and the eluent was evaporated, yielding 8.5 parts (100%) of 3-[2-[4-(6fluoro-1,2-benzisoxazol-3-yl)-1-piperidinyl]ethyl]-6,7,8,9-tetrahydro-7-methoxy-2-methyl-4H-pyrido[1,2a]-pyrimidin-4-one as an oily residue. (intermediate 5)

B. Final Compounds

EXAMPLE 3

A mixture of 12.5 parts of 3-(2-chloroethyl)-6,7,8,9tetrahydro-9-hydroxy-4H-pyrido[1,2-a]pyrimidin-4-one, 10.0 parts of 6-fluoro-3-(4-piperidinyl)-1,2-ben16

zisoxazole monohydrochloride, 10 parts of N-(1methylethyl)-2-propanamine and 120 parts of methanol was stirred overnight at 60° C. The reaction mixture was evaporated and the oily residue was taken up in trichloromethane and washed with water. The organic layer was dried, filtered and evaporated. The residue was purified twice by column chromatography over silica gel first using a mixture of trichloromethane and methanol (95:5 by volume) and then a mixture of trichloromethane and methanol, saturated with ammonia (95:5 by volume) as eluents. The pure fractions were collected and the eluent was evaporated. The residue was crystallized from 2-propanone. After cooling, the precipitated product was filtered off, washed with a mixture of 2-propanol and 2,2'-oxybispropane and recrystallized from 2-propanol. The product was filtered off and dried, yielding 3.6 parts (21.1%) of 3-[2-[4-(6fluoro-1,2-benzisoxazol-3-yl)-1-piperidinyl]ethyl]-6,7,8,9-tetrahydro-9-hydroxy-2-methyl-4H-pyrido[1,2a]pyrimidin-4-one; mp. 179.8° C. (Compound 1)

EXAMPLE 4

To a stirred solution of 5.4 parts of 3-[2-[4-(6-fluoro-1,2-benzisoxazol-3-yl)-1-piperidinyl]ethyl]-6,7,8,9-tetrahydro-9-hydroxy-2-methyl-4H-pyrido[1,2-a]-pyrimidin-4-one and 1.6 parts of N,N-dimethyl-4-pyridinamine in 39 parts of dichloromethane was added dropwise a solution of 5.4 parts of (+)-3,4-dihydro-1H-2-benzopyran-2-carbonyl chloride in 39 parts of dichloromethane. Upon complete addition, stirring was continued for 4 hours at room temperature. The reaction mixture was washed successively with water, a sodium hydroxide solution 1N and water, dried, filtered and evaporated. The residue was purified by column chromatography over silica gel using a mixture of acetonitrile and water, saturated with ammonia (50:50 by volume) as eluent. Two pure fractions were collected and the eluent was evaporated. Each residue was salted out with sodium chloride and two diastereo-isomeric esters were obtained. The first isomer was combined with 16 parts of methanol, 1 parts of N-(1-methyl-ethyl)-2-propanamine and I part of water and the whole was stirred for 160 minutes at 60° C. The mixture was evaporated and the residue was purified by column chromatography over silica gel using a mixture of trichloromethane and methanol (90:10 by volume) as eluent. The pure fractions were collected and the eluent was evaporated. The residue was crystallized from 2-propanol. The product parts of N-(1-methylethyl)--2-propanamine and 16 parts 50 was filtered off and dried, yielding 0.2 parts (3.6%) of (+)-3-[2-[4-(6-fluoro-1,2-benzisoxazol-3-yl)-1piperidinyl]ethyl]-6,7,8,9-tetrahydro-9-hydroxy-2methyl-4H-pyrido[1,2-a]-pyrimidin-4-one; mp. 160.7°

C., $[a]^D = +15.42^{\circ}$ (c=0.5% in ethanol). (Compound 2) The second isomer was combined with 16 parts of methanol, 1 part of N-(1-methylethyl)-2-propanamine and I part of water and the whole was stirred for 160 minutes at 60° C. The mixture was evaporated and the residue was purified by column chromatography over silica gel using a mixture of trichloromethane and methanol (90:10 by volume) as eluent. The pure fractions were collected and the eluent was evaporated. The residue was crystallized from 2-propanol. The product was filtered off and dried, yielding 0.2 parts (3.6%) of (-)-3-[2-[4-(6-fluoro-1,2-benzisoxazol-3-yl)-1-

piperidinyl]ethyl]6,7,8,9-tetrahydro-9-hydroxy-2-methyl-4H-pyrido[1,2-a]-pyrimidin-4-one; mp. 156.9° C. $[a]_{c}^{D} = -22.81^{\circ}$ C. (c=0.5% in ethanol). (Compound 3)

EXAMPLE 5

A mixture of 4.3 parts of 3-[2-[4-(6-fluoro-1,2-benzisoxazol-3-yl)-1-piperidinyl]-ethyl]-6,7,8,9-tetrahydro-9-hydroxy-2-methyl-4H-pyrido[1,2-a]pyrimidin-4-one and 30 parts of acetic acid anhydride was stirred for 4 hours at 50° C. After cooling, the reaction mixture was poured into water and treated with an ammonium hydroxide solution. The product was extracted with 4methyl-2-pentanone. The extract was dried, filtered and 10 evaporated. The residue was purified by column chromatography over silica gel using a mixture of trichloromethane and methanol (95:5 by volume) as eluent. The pure fractions were collected and the eluent was evaporated in vacuo. The residue was crystallized from 2,2'- 15 oxybispropane. The product was filtered off and dried, yielding 3.0 parts (64.0%) of 3-[2-[4-(6-fluoro-1,2-benzisoxazol-3-yl)-1-piperidinyl]ethyl]-6,7,8,9-tetrahydro-2-methyl-4-oxo-4H-pyrido[1,2-a]pyrimidin-9acetate(ester); mp. 143.6° C. (Compound 4) In a similar 20 manner and by using butanoic acid anhydride as acylating reagent there was also prepared [3-[2-[4-(6-fluoro-1,2-benzisoxazol-3-yl)-1-piperidinyl]ethyl]-6,7,8,9-tetrahydro-2-methyl-4-oxo-4H-pyrido[1,2-a]pyrimidin-9yl]butanoate, mp. 112.9° C. (Compound 5).

EXAMPLE 6

To a stirred solution of 1.2 parts of 3-[2-[4-(6-fluoro-1,2-benzisoxazol-3-yl)-1-piperidinyl]ethyl]-6,7,8,9-tetrahydro-9-hydroxy-2-methyl-4H-pyrido[1,2-a]pyrimidin-4-one in 21 parts of dichloromethane and 5 parts of water were simultaneously added dropwise a solution of 1.1 parts of decanoyl chloride in 13 parts of dichloromethane and a solution of 1 part of sodium hydroxide in 6 parts of water. Upon complete addition, stirring was 35 continued for 2 hours at room temperature. Another portion of 1.1 parts of decanoyl chloride was added and stirring was continued overnight at room temperature. The product was extracted with dichloromethane. The extract was washed with water, dried, filtered and 40 evaporated. The residue was purified by column chromatography over silica gel using a mixture of trichloromethane and methanol (95:5 by volume) as eluent. The pure fractions were collected and the eluent was evaporated. The residue was converted into the hydrochlo- 45 ride salt in 2-propanol. The product was filtered off and dried, yielding 0.9 parts (45.9%) of [3-[2-[4-(6-fluoro-1,2-benzisoxazol-3-yl)-1-piperidinyl]ethyl]-6,7,8,9-tetrahydro-2-methyl-4-oxo-4H-pryrido[1,2-a]pyrimidin-9yl]decanoate dihydrochloride; mp. 221.4° C. (Com- 50 pound 6)

EXAMPLE 7

A mixture of 8.5 parts of 3-[2-[4-(6-fluoro-1,2-ben-zisoxazol-3-yl)-1-piperidinyl]-ethyl]-6,7,8,9-tetrahydro-7-methoxy-2-methyl-4H-pyrido[1,2-a]pyrimidin-4-one, 14 parts of iodotrimethylsilane and 40 parts of acetonitrile was stirred overnight at 70° C. Another portion of 2,8 parts of iodotrimethylsilane was added and the reaction mixture was stirred for a while at 90° C. and then 60 overnight at reflux temperature. After cooling, the whole was evaporated. The residue was taken up in ethanol and the whole was evaporated again. The residue was taken up in water and treated with a sodium hydroxide solution. The product was extracted with 65 trichloromethane. The extract was dried, filtered and evaporated. The residue was purified by column chromatography over silica gel using a mixture of trichloro-

methane and methanol (95:5 by volume) as eluent. The desired fraction was collected and the eluent was evaporated. The residue was solidified in ethanol. The product was filtered off and dried, yielding 0.3 parts (3.7%) of 3-[2-[4-(6-fluoro-1,2-benzisoxazol-3-yl)-1-piperidinyl-lethyl]-6,7,8,9-tetrahydro-7-hydroxy-2-methyl-4H-pyrido[1,2-a]-pyrimidin-4-one; mp. 156.2° C. (Compound 7)

Following the procedure of example 6, compound 7 was converted to [3-[2-[4-(6-fluoro-1,2-benzisoxazol-3-yl)-1-piperidinyl]ethyl]-6,7,8,9-tetrahydro-2-methyl-4-oxo-4H-pyrido[1,2-a]-pyrimidin-7-yl]decanoate. (Compound 8)

C. Pharmacological Examples

EXAMPLE 8

The antipsychotic activity of the subject compounds is evidenced by the experimental data obtained in at least one of two different test procedures, viz. the combined apomorphine (APO), tryptamine (TRY) and norepinephrine (NOR) test in rats, and the apomorphine test in dogs. Said combined apomorphine, tryptamine and norepinephrine test is described in Ach. int. Phar-25 macodyn., 227, 238-253 (1977) and provides an empirical evaluation of the relative specificity with which drugs may effect particular neurotransmitter systems centrally (CNS) as well as peripherally. In particular, the test demonstrates the antagonistic activity of the tested compounds of formula (I) on dopamine (by preventing the symptoms elicited with the dopamine agonist apomorphine), on serotonin (by preventing the central and peripheral symptoms (convulsions; hyperaemia) elicited with serotonin or tryptamine), and on norepinephrine (by preventing or delaying death upon administration of the a2-agonist norepinephrine). Said apomorphine test in dogs is described in Arzneim-Forsch. (Drug Res.), 9, 765-767 (1959) and provides a measure of the duration of action of the tested compounds. The tests are carried out following the procedures described in EP-A-0,196,132 and the experimental data are summarized in Table 1.

TABLE 1

	Combined test in rats; ED50 in mg/kg						
Comp		(TRY)- convul-	(TRY)- hyper-		(APO)-dog test, ED50 in mg/kg		
No.	(APO)	sions	aemia	(NOR)	1 hr	4 hr	16 hr
1	0.25	0.31	0.002	0.08	0.015	0.015	0.015
2	0.31	0.08	0.00031	1.25	0.015	0.03	0.06
3	0.31	0.33	0.00063	0.63	0.008	0.007	0.015
4	0.31	0.08	0.00031	0.31	0.015	•	•
5	0.31	0.31	0.00125	0.16	0.008	•	•

not tested

D. Composition Examples

EXAMPLE 9

Oral Drops

500 Parts of the A.I. was dissolved in 0.5 l of 2-hydroxypropanoic acid and 1.5l of the polyethylene glycol at 60° ~80° C. After cooling to 30° ~40° C. there were added 35 l of polyethylene glycol and the mixture was stirred well. Then there was added a solution of 1750 parts of sodium saccharin in 2.5 l of purified water and while stirring there were added 2.5 l of cocoa flavor and polyethylene glycol q.s. to a volume of 50 l, providing an oral drop solution comprising 10 mg/ml of A.I.

The resulting solution was filled into suitable contain-

EXAMPLE 10

Oral Solution

9 Parts of methyl 4-hydroxybenzoate and 1 part of propyl 4-hydroxybenzoate were dissolved in 41 of boiling purified water. In 311 of this solution were dissolved first 10 parts of 2,3-dihydroxybutanedioic acid and thereafter 20 parts of the A.I. The latter solution was combined with the remaining part of the former solution and 12 I 1,2,3-propanetriol and 3 I of sorbitol 70% solution were added thereto. 40 Parts of sodium saccharin were dissolved in 0.5 l of water and 2 ml of raspberry and 2 ml of gooseberry essence were added. The latter solution was combined with the former, water was added q.s. to a volume of 201 I providing an oral solution comprising 5 mg of the active ingredient per teaspoonful (5 ml). The resulting solution was filled in 20 suitable containers.

EXAMPLE 11

Capsules

parts starch, 56 parts lactose, 0.8 parts colloidal silicon dioxide, and 1.2 parts magnesium stearate were vigorously stirred together. The resulting mixture was subsequently filled into 1000 suitable hardened gelatin capsules, comprising each 20 mg of the active ingredient. 30

EXAMPLE 12

Film-Coated Tablets

Preparation of tablet core

A mixture of 100 parts of the A.I., 570 parts lactose and 200 parts starch was mixed well and thereafter humidified with a solution of 5 parts sodium dodecyl sulfate and 10 parts polyvinylpyrrolidone (Kollidon-K 90 ®) in about 200 ml of water. The wet powder mixture was sieved, dried and sieved again. Then there was added 100 parts microcrystalline cellulose (Avicel ®) and 15 parts hydrogenated vegetable oil (Sterotex (R)). The whole was mixed well and compressed into tablets, giving 10.000 tablets, each containing 10 mg of the 45 tive amount of the compound of claim 1. active ingredient.

Coating

To a solution of 10 parts methyl cellulose (Methocel 60 HG (R) in 75 ml of denaturated ethanol there was added a solution of 5 parts of ethyl cellulose (Ethocel 22 cps (R) in 150 ml of dichloromethane. Then there were added 75 ml of dichloromethane and 2.5 ml 1,2,3propanetriol. 10 Parts of polyethylene glycol was mollatter solution was added to the former and then there were added 2.5 parts of magnesium octadecanoate, 5 parts of polyvinylpyrrolidone and 30 ml of concentrated colour suspension (Opaspray K-1-2109®) and the whole was homogenated. The tablet cores were 60 20

coated with the thus obtained mixture in a coating apparatus.

EXAMPLE 13

Injectable Solution

1.8 Parts methyl 4-hydroxybenzoate and 0.2 parts propyl 4-hydroxybenzoate were dissolved in about 0.51 of boiling water for injection. After cooling to about 50° C. there were added while stirring 4 parts lactic acid, 0.05 parts propylene glycol and 4 parts of the A.I.. The solution was cooled to room temperature and supplemented with water for injection q.s. ad 1 l, giving a solution comprising 4 mg/ml of A.I.. The solution was sterilized by filtration (U.S.P. XVII p. 811) and filled in sterile containers.

EXAMPLE 14

Suppositories

3 Parts A.I. was dissolved in a solution of 3 parts 2,3-dihydroxybutanedioic acid in 25 ml polyethylene glycol 400. 12 Parts surfactant (SPAN ®) and triglycerides (Witepsol 555 ®) q.s. ad 300 parts were molten together. The latter mixture was mixed well with the 20 Parts of the A.I., 6 parts sodium lauryl sulfate, 56 25 former solution. The thus obtained mixture was poured into moulds at a temperature of 37°-38° C. to form 100 suppositories each containing 30 mg/ml of the A.I.

EXAMPLE 15

Injectable Solution

60 Parts of A.I. and 12 parts of benzylalcohol were mixed well and sesame oil was added q.s. ad 1 l, giving a solution comprising 60 mg/ml of A.I. The solution was sterilized and filled in sterile containers.

We claim:

- 1. A compound selected from the group consisting of a C2-20alkanoic acid ester of 3-[2-[4-(6-fluoro-1,2-benzisoxazol-3-yl)-1-piperidinyl]ethyl]-6,7,8,9-tetrahydro-9-hydroxy-2-methyl-4H-pyrido[1,2-a]pyrimidin-4-one,
- a pharmaceutically acceptable acid addition salt thereof, and an enantiomeric form thereof.
- 2. An antipsychotic composition comprising an inert carrier and as active ingredient an antipsychotic effec-
- 3. A method of treating warm-blooded animals suffering from psychotic diseases, which method comprises the administration to said warm-blooded animals of an antipsychotic effective amount of the compound of claim 1.
- 4. The compound of claim 1 wherein the alkanoic acid is octanoic acid, decanoic acid, dodecanoic acid, or tetradecanoic acid.
- 5. The composition of claim 2 wherein the alkanoic ten and dissolved in 75 ml of dichloromethane. The 55 acid is octanoic acid, decanoic acid, dodecanoic acid, or tetradecanoic acid.
 - 6. The method of claim 3 wherein the alkanoic acid is octanoic acid, decanoic acid, dodecanoic acid, or tetradecanoic acid.

Exhibit 3

Copy of U.S. Patent & Trademark Office Maintenance Fee Statement for U.S. Patent No. 5.254.556



Patent Bibliographic Data	5254556			06/24/2009 1	
Patent Number:	5254556		Application Number:	07932142	
Issue Date:	10/19/1993		Filing Date:	08/19/1992	
Title:	NOVEL 3-1	PIPERIDINYL-1,2-	BENZISOXAZOLES		
Status:	4th, 8th and	12th year fees paid		Entity:	Large
Window Opens:	N/A	Surcharge Date:	N/A	Expiration:	N/A
Fee Amt Due:	Window not open	Surchg Amt Due:	Window not open	Total Amt Due:	Window not open
Fee Code:				and the second s	<u> </u>
Surcharge Fee Code:					
Most recent events (up to 7):	03/16/2001	Payment of Mainte	nance Fee, 8th Year, Lar, nance Fee, 4th Year, Lar,	ge Entity.	***************************************
Address for fee purposes:	JOHNSON ONE JOHN	A. CIAMPORCERO AND JOHNSON SON AND JOHNSON NSWICK, NJ		rge Entity.	
Run Another Query					





Commissioner for Patents United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450 www.uspto.gov

Customer No 000000

ISTMT

DATE PRINTED 06/25/2009

AUDLEY A. CIAMPORCERO JOHNSON AND JOHNSON ONE JOHNSON AND JOHNSON PLAZA NEW BRUNSWICK NJ 08933-7003

MAINTENANCE FEE STATEMENT

According to the records of the U.S.Patent and Trademark Office (USPTO), the maintenance fee and any necessary surcharge have been timely paid for the patent listed below. The "PYMT DATE" column indicates the payment date (i.e., the date the payment was filed).

The payment shown below is subject to actual collection. If the payment is refused or charged back by a financial institution, the payment will be void and the maintenance fee and any necessary surcharge unpaid.

Direct any questions about this statement to: Mail Stop M Correspondence, Director of the USPTO, P.O.Box 1450, Alexandria, VA 22313-1450.

5,254,556	\$1,020.00	\$0.00	03/25/97	07/932,142	10/19/93	08/19/92	04	NO	JAB-828	
PATENT NUMBER	FEE AMT	SUR CHARGE	PYMT DATE	U.S. APPLICATION NUMBER	PATENT ISSUE DATE	APPL. FILING DATE	PAYMENT YEAR	SMALL ENTITY?	ATTY DKT NUMBER	

UNITED STATES PATENT AND TRADEMARK OFFICE



Commissioner for Patents United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450 www.uspto.gov

Customer No 000000

ISTMT

DATE PRINTED 06/25/2009

AUDLEY A. CIAMPORCERO JOHNSON AND JOHNSON ONE JOHNSON AND JOHNSON PLAZA NEW BRUNSWICK NJ 08933-7003

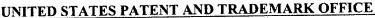
MAINTENANCE FEE STATEMENT

According to the records of the U.S.Patent and Trademark Office (USPTO), the maintenance fee and any necessary surcharge have been timely paid for the patent listed below. The "PYMT DATE" column indicates the payment date (i.e., the date the payment was filed).

The payment shown below is subject to actual collection. If the payment is refused or charged back by a financial institution, the payment will be void and the maintenance fee and any necessary surcharge unpaid.

Direct any questions about this statement to: Mail Stop M Correspondence, Director of the USPTO, P.O.Box 1450, Alexandria, VA 22313-1450.

PATENT NUMBER	FEE AMT	SUR CHARGE	PYMT DATE	U.S. APPLICATION NUMBER	PATENT ISSUE DATE	APPL. FILING DATE	PAYMENT YEAR	SMALL ENTITY?	ATTY DKT NUMBER	
5,254,556	\$1,950.00	\$0.00	03/16/01	07/932,142	10/19/93	08/19/92	08	NO	JAB-828	





Commissioner for Patents United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450 www.uspto.gov

Customer No 000000

ISTMT

DATE PRINTED 06/25/2009

AUDLEY A. CIAMPORCERO JOHNSON AND JOHNSON ONE JOHNSON AND JOHNSON PLAZA NEW BRUNSWICK NJ 08933-7003

MAINTENANCE FEE STATEMENT

According to the records of the U.S.Patent and Trademark Office (USPTO), the maintenance fee and any necessary surcharge have been timely paid for the patent listed below. The "PYMT DATE" column indicates the payment date (i.e., the date the payment was filed).

The payment shown below is subject to actual collection. If the payment is refused or charged back by a financial institution, the payment will be void and the maintenance fee and any necessary surcharge unpaid.

Direct any questions about this statement to: Mail Stop M Correspondence, Director of the USPTO, P.O.Box 1450, Alexandria, VA 22313-1450.

PATENT NUMBER	FEE AMT	SUR CHARGE	PYMT DATE	U.S. APPLICATION NUMBER	PATENT ISSUE DATE	APPL. FILING DATE	PAYMENT YEAR	SMALL ENTITY?	ATTY DKT NUMBER
5 254.556	\$3.800.00	\$0.00	03/29/05	07/932,142	10/19/93	08/19/92	12	NO	JAB-828

Exhibit 4

Terminal Disclaimer filed in U.S. Patent No. 5.254.556

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant

Cornelius G. M. Janssen et al.

Serial No.

07/932,142

Art Unit:

1202

Filed

August 19, 1992

Examiner:

J. Venkat

For

NOVEL 3-PIPERIDINYL-1,2-BENZISOXAZOLES

Honorable Commissioner of Patents and Trademarks Washington, D.C. 20231

Sir:

TERMINAL DISCLAIMER

Your Petitioner, JANSSEN PHARMACEUTICA N.V., a corporation of Belgium, having an address at Turnhoutseweg 30, B-2340 Beerse, Belgium, represents that it is the Assignee of the entire right, title and interest in and to the subject matter disclosed in the above-captioned patent application by virtue of its being a divisional of U.S. Patent Application Serial No. 07/422,847, filed October 17, 1989, which was assigned to JANSSEN PHARMACEUTICA N.V., the assignment being recorded in the United States Patent and Trademark Office on November 13, 1989, on Reel 5171, Frame 0567.

Your Petitioner, JANSSEN PHARMACEUTICA N.V., hereby disclaims, under the provisions of 35 U.S.C. 253, the terminal part of any patent granted on application Serial No. 07/932,142 which would extend beyond the expiration date of United States Patent No. 5,158,952, also assigned to JANSSEN PHARMACEUTICA N.V. (recorded on November 13, 1989, on Reel 5171, Frame 0567), and hereby agrees that any patent so granted on application Serial No. 07/932,142 shall be enforceable only for and during such period that the legal title of said patent shall be the same as the legal title to United States Patent No. 5,158,952, this agreement to run with any patent granted on application Serial No. 07/932,142 and to be binding upon the grantee, its successors or assigns.

Signed at Beerse (Belgium) this 7th day of December, 1992.

Respectfully submitted,

JANSSEN PHARMACEUTICA N.V.

Wantet
December 7, 1992

Dirk Wante

Head Patent Department, Proxy Holder

Charles J. Metz Attorney for Applicants Reg. # 20,359 Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003

(908) 524-2814

Claims 1, 2 and 3 of U.S. Patent No. 5,254,556 Claim the Active Ingredient of the Product Seeking Approval or its Method of Use

1.	A compound selected from the group consisting of a C_{2-20} alkanoic acid ester of 3-[2-[4-(6-fluoro-1,2-benzisoxazol-3-yl)-1-piperidinyl]ethyl]- 6,7,8,9-tetrahydro-9-hydroxy-2-methyl-4H-pyrido[1,2-a]pyrimidin-4-one, a pharmaceutically acceptable acid addition salt thereof, and an enantiomeric form thereof.	Paliperidone palmitate is a C ₁₆ alkanoic acid ester of 3-[2-[4-(6-fluoro-1,2-benzisoxazol-3-yl)-1-piperidinyl]ethyl]- 6,7,8,9-tetrahydro-9-hydroxy-2-methyl-4H-pyrido[1,2-a]pyrimidin-4-one.
2.	An antipsychotic composition comprising an inert carrier and as active ingredient an antipsychotic effective amount of the compound of claim 1.	The Product currently undergoing regulatory review comprises paliperidone palmitate, a C ₁₆ alkanoic acid ester of 3-[2-[4-(6-fluoro-1,2-benzisoxazol-3-yl)-1-piperidinyl]ethyl]- 6,7,8,9-tetrahydro-9-hydroxy-2-methyl-4H-pyrido[1,2-a]pyrimidin-4-one, and one or more inert carriers provided in an amount sufficient to treat schizophrenia (a psychotic disorder).
3.	A method of treating warm-blooded animals suffering from psychotic diseases, which method comprises the administration to said warm-blooded animals of an antipsychotic effective amount of the compound of claim 1.	The Product is currently undergoing regulatory review for the treatment of schizophrenia (a psychotic disease). The treatment comprises administering an antipsychotic effective amount of paliperidone palmitate, a C ₁₆ alkanoic acid ester of 3-[2-[4-(6-fluoro-1,2-benzisoxazol-3-yl)-1-piperidinyl]ethyl]- 6,7,8,9-tetrahydro-9-hydroxy-2-methyl-4H-pyrido[1,2-a]pyrimidin-4-one.

Exhibit 6

Description of Significant Activities of Applicant during Regulatory Review

Gateway Receipt **国国国** g ق ق ā 밀밀 <u>කි</u> කි 뗭 g g 8 8 8 8 g 열 열 열 æ 밀밀멸 ם g na na a a ā 밀 ခ **8** 8 쪌 EDMS-PSDB-3902895 EDMS-PSDB-3907677 EDMS-PSDB-3909784 EDMS-PSDB-3928113 EDMS-PSDB-3548304 EDMS-PSDB-3474299 EDMS-PSDB-3479851 EDMS-PSDB-3514273 EDMS-PSDB-3594054 EDMS-PSDB-2931978 EDMS-PSDB-2937288 EDMS-PSDB-3044512 EDMS-PSDB-3818660 EDMS-PSDB-3928067 EDMS-PSDB-3862824 EDMS-PSDB-3868773 EDMS-PSDB-2651976 EDMS-PSDB-3195694 EDMS-PSDB-3288697 EDMS-PSDB-3397560 EDMS-PSDB-3442328 EDMS-PSDB-3599384 EDMS-PSDB-3681428 EDMS-PSDB-3699361 EDMS-PSDB-3704542 EDMS-PSDB-3723435 EDMS-PSDB-3732055 EDMS-PSDB-3776556 EDMS-PSDB-3756672 EDMS-PSDB-3810109 EDMS-PSDB-3860095 EDMS-PSDB-2656702 EDMS-PSD8-2683477 EDMS-PSD8-2697285 EDMS-PSDB-3728621 EDMS-PSDB-2716903 EDMS-PSDB-3230681 3902895 3907677 3909784 3928113 3699361 3704542 3723435 3728621 3818660 3928067 3862824 3474299 3479851 3514273 3594054 3756672 3810109 2716903 2931978 2937288 3044512 3230681 3288697 3397560 3609437 3681428 3776556 3732055 3860095 3868773 2683477 2697285 3599384 3195694 2651976 2656702 Multiple Sequence EDMS or 012 013 014 017 018 020 020 E 22 82 016 028 028 029 024 25 na 026 8 8 8 8 9888 015 멸 8 8 E пa g ŧ g ā ā R092670-SCH-201 R092670-SCH-201 R092670-SCH-201 R092670-SCH-201 R092677-SCH-304 R076477-PSY-3004 na R092670-SCH-704 R076477-SCH-303 R076477-SCH-303 R092670-SCH-201 R076477-SCH-304 R092670-SCH-201 na R092670-USA-3 B ā 2 2 Ē na g 굗 열 열 g 밑 Ē ē ä g ē ä g g g 麔 ā Request for List of Nonclinical Studies Submitted Under IND Briefing Package for 6/16/04 CMC/Biopharm Meeting Minutes of 6/16/04 CMC/Biopharmaceutics End of Phase 2 Briefing Package for 9/28/04 End of Phase 2 Meeting Request for Special Protocol Assessment: Carcnogenicity Notice of Intent to Request Special Protocol Assessment: Fax: 10/26/04 Submission SN 024 Minutes of the 9/28/04 End of Phase 2 Meeting and Post-Request for Type B End of Phase 2 Meeting - Chemistry, Fax: Response to Carcinogenicity Protocol Assessment Request - Final CAC Report Request for Additional Desk Copies and IND Number for Response to FDA Request in 10/12/04 End of Phase 2 Follow-up Information for Request for Special Protocol Minutes of the 9/28/04 End of Phase 2 FDA Meeting Minutes of 6/16/04 Type B End of Phase 2 Meeling Clearance to Proceed with the Studies Under IND Response to Request by Review Chemist Carcinogenicity
Fax: Notice of Intent to Request Special Protocol Letter: Meeting Request Granted for 6/16/04 Request for a Type B End-of-Phase 2 Meeting Response to Request from Dr. Lois Freed Response to Request by Review Chemis Assessment: Carcinogenicity Protoco Assessment: Carcinogenicity SN 021 etter: IND Acknowledgement Letter Microbiology, and Biopharmaceutics Meeting for Paliperidone palmitate Reporting Period: 6/7/03 - 6/6/04 IN-JNJFOC-20040800656 Initial JS-JNJFOC-20041100394 Initial CMC/Biopharm Meeting Minutes New Protocol; New Investigator New Investigators US-JNJFOC-20040304794 Initial CMC; Pharmacology/Toxicology US-JNJFOC-20040304794 F-1 Request for a Type C Meeting New Protocol, New Investigator Meeting Follow-up Information N-JNJFOC-20040800656 Original IND (50 Volumes CMC/Biopharmceutics New Investigators New Investigators New Investigators New Investigators New Investigators Profocol na na na na 6/16/2004 5/13/2003 9/28/2004 5/19/2003 na 7/2003 2 2 2 2 E 8 8 8 8 8 8 8 8 8 g <u>ක</u> කි ā Contact 8 8 8 8 8 8 8 8 ä g Date of g General Correspondence Correspondence Information Amendmen FDA Correspondence FDA Correspondence FDA Correspondence FDA Correspondence Submission Type 11/9/2004 Protocol Amendment Record of Contact IND Amendment IND Amendment IND Amendment Annual Report Safety Report Safety Report Safety Report Safety Report Safety Repor Original IND General 11/10/2004 0/26/2004 11/15/2004 10/27/2004 0/28/2004 3/31/2004 8/25/2004 0/26/2004 6/5/2003 9/11/2003 9/12/2003 10/28/2003 1/23/2004 7/1/2004 8/4/2004 9/9/2004 0/26/2004 8/27/2004 6/2/2003 2/11/2004 5/6/2004 5/20/2004 6/16/2004 6/28/2004 8/17/2004 5/19/2003 1/9/2004 4/29/2004 9/2/2004 5/13/2007

304 033 304 031 304 033 304 033 304 033 304 033 305 033 306 033 307 038 307 038 308 039 308 040 309 040 300 060 300 040 300 060 300		הסום ח		a leading		# D2 B70B7		
Single Player 18 SCALLOCOCOCHITICOST MINISTRATION MINIST		Contact			o	3928878	EDMS-PSDB-3928878	na
Statush Pagort In B. Park Co. 2001 (1987) F. Pagort (1987) CORP (1987) Statush Pagort CORP (1987) Statush Pagort CORP (1987) Statush Pagort CORP (1987) CORP (1987) Statush Pagort CORP (1987)	****	па		B076477-SCH-304	331	3931421	EDMS-PSDB-3931421	na
State Programment Tea 18, 144 Processory (1994) Hintal RODINATE SCHOOL (1994) CONTRICTOR	_	na	US-JNJFOC-20041102371 Initial	0076477 SCH 304	333	3938295	EDMS-PSDB-3938295	na
Figh Contragonation To a State regard No. Property Schools Costs State Costs	┯	na	Ψĺ	HO/04/1/30/H-30/	3 8	3961743	EDMS-PSDB-3961743	na
Stable Pageon 10 System National Control Cont	-	па	- t	HU/04//-3CH-304	33.5	3949874	EDMS-PSDB-3949874	na
Modernation of the Control o	_	па		HU/64//-30-1-304	388	3955196	FDMS-PSDB-3955196	na
Salety Report n. IO_AMPCO_2001105548 initial PROPERTY SCHAROL ROS (2007) SSERIOR TOWN PROPERTY SCHAROL TOWN PROPERTY SCHAROL <td>-</td> <td>na</td> <td></td> <td>102 1130 201</td> <td>3 8</td> <td>3061376</td> <td>FDMS-PSDB-3961376</td> <td>na</td>	-	na		102 1130 201	3 8	3061376	FDMS-PSDB-3961376	na
Sales Megont na MY-AMPO COMONITORS Initial HORSENT SCHOOL 1000 1987 173 EDMS-PRISE - 2012 FOR STREAM COMMENT TOWN PROPERTY OF THE STREAM COMMENT	+-	na		HO/64//-50H-504	38	3063269	FDMS-PSDB-3963269	Tâ
Substitutional Amendment na. Paramatoological Principal ROBERTY SCH-700 098 SPREAT EDMS-PSD-200-2015 13.1 Substitutional Amendment na. US-ANI-FOC-CANAL 200-61 minal ROBERTY SCH-700 0.04 4988977 EDMS-PSD-200-200-200-200-200-200-200-200-200-20	1	æ		HU/64//-3CH-/13	237	3067273	FDMS-PSDB-3967273	na
Substitute of the place of the pla	+	na		na Dozesta COLL 704	38	3076131	FDMS-PSDB-3976131	na
State between In MANIA (1970-2000) (1970-1980-1980) HUMATT/2001-100 CONTRINGED EDMS-1980-1980-1980-1990 State between In Behild Placesty (17.190-Name) HUMATT/2001-100 vol. 0000000 EDMS-1980-1000000 EDMS-1980-100000 State between In MANIA (1970-2004) (1973-16-7) HUMATT/2001-100 vol. 0000000 EDMS-1980-1000000 EDMS-1980-10000000 EDMS-1980-1000000 EDMS-1980-10000000 EDMS-1980-1000000 EDMS-1980-10000000 EDMS-1980-10000000 EDMS-1980-10000000 EDMS-1980-1000000000000000000000000000000000	+	na		H0/64//-SCH-/01	200	2008107	EDMS-PSDB-3998127	na
	-1-	Da.	IN-JNJFOC-20041202092 Initial	R076477-SCH-703	200	3930127	EDMS-PSDR-3998804	na
State Processor Fig. ALTANIC CORROLAGES (Initial) RIVANITY SCH-1700 CORRESPONDED (INITIAL CORROLAGES) FINAL PROCESSOR CORRESPONDED (INITIAL CORROLAGES) FINAL PROCESSOR (INITIAL CORROLAGES)		ļ	Briefing Package for 1/13/05 Meeting	na	g :	3998604	EDIMS-I SDB SSSSSS	na Ua
Salety Report na W/W.MIPCO-2004102594 F-1 R/W.MIPCO-2004102594 F-2 R/W.MIPCO-2004102594 F-2 R/W.MIPCO-2004102594 F-2 R/W.M.M.M.M.M.M.M.M.M.M.M.M.M.M.M.M.M.M.M	-	\downarrow	CA. IN IEOC. 20041204345 Initial	R076477-SCH-305	941	4008929	ECIMO-FOLD 400369	a c
Salety Report na MYANTICC 2004/120038 F.1 RPINEATY:SCHYND 6.44 40103696 EUMS-STREATH (1986) 0.1 A 40103696 EUMS-STREATH (1986) 0.1 A 40103696 EUMS-STREATH (1986) 0.1 A 40103696 EUMS-STREATH (1986) 0.1 0.1 A 4010369 EUMS-STREATH (1986) 0.1 A 4010369 EUMS-STREATH (1986) 0.1 A 4010369 EUMS-STREATH (1986) EUMS-STREATH (1986) EUMS-STREATH (1986) EUMS-STREATH (1986) 0.1	_	2	MV. IN IEOC. 20041105754 F-1	R076477-SCH-705	945	4007899	EUMS-PSUB-4007639	0.00
Salety Report ria MYALNE/OCZONI/20028 F-1 RODGATYSCH-700 644 4010866 EDNAS-PSEB-4010969 Salety Report ria MYALNE/OCZONI/20032 F-1 RODGATYSCH-700 404 4010867 EDNAS-PSEB-4010969 Salety Report ria MYALNE/OCZONI/20032 F-1 RODGATYSCH-700 404 4019867 EDNAS-PSEB-4019967 Salety Report ria MYALNE/OCZONI/20036 F-1 RODGATYSCH-700 402 4019867 EDNAS-PSEB-4019967 Salety Report ria USALINI/COCZONI/100784 F-1 RODGATYSCH-700 605 4026271 EDNAS-PSEB-4026071 Salety Report ria USALINI/COCZONI/100784 F-1 RODGATYSCH-701 605 4026271 EDNAS-PSEB-4026071 Salety Report ria USALINI/COCZONI/100784 F-2 RODGATYSCH-701 605 4056279 EDNAS-PSEB-4026071 Salety Report ria Salety Report ria Salety Report ria FOLOSATYSCH-701 605 4056279 EDNAS-PSEB-402671 Salety Report ria Salety Report ria FOLOSATYSCH-700 605 <td></td> <td>200</td> <td>MIT-UNOT CO-2004 1000 CO. IN TEOC. 2004 120 Initial</td> <td>R076477-SCH-705</td> <td>043</td> <td>4010952</td> <td>EDMS-PSDB-4010952</td> <td>I G</td>		200	MIT-UNOT CO-2004 1000 CO. IN TEOC. 2004 120 Initial	R076477-SCH-705	043	4010952	EDMS-PSDB-4010952	I G
State Report na MYALAN COCZOGATIONSTS F-2 FROTEATY SQL-100 OAS 40109867 EDIAS FSDB-4010090 DATA COCZOGATIONSTS F-2 Reconsory Respondent na CANALIZOC ZOMONITORSTS F-1 ROPERTY SQL-100 OAT 40109807 EDIAS FSDB-40110900 DATA RECONSORY TO A TO	- 1	E	IN 181 EOC 2004 2020 E.1	R076477-SCH-703	044	4010959	EDMS-PSDB-4010959	DG .
Salety Report rate MY-AUNCOCCOLOGNATIONS FROPEAT/SCH-1096 Odd 4016867 EDIMS-FORDER Salety Report rate MY-AUNCOCCOLOGNATIONS FROPEAT/SCH-109 Odd 4016867 EDIMS-FORDER FROM STABLE Salety Report rate New Processor Report TS-SCH-100 OGG FROM STABLE		22		R076477-SCH-705	045	4010966	EDMS-PSDB-4010966	na
Saley Report The National New Investigation ANAMATICA CONTRIBUTION FROM ATTAINS		g L		R076477-SCH-305	940	4019867	EDMS-PSDB-4019867	пã
Politocol Amendment na Medical Processor Female Report Female Re		g	CA-NUT-CC-2004 IZOSTISSISSI	R092670-PSY-3001	047	4023920	EDMS-PSDB-4023920	па
Salety Report na WANNINCO-2200411003294 Fr.3 FROP #477-SCH-703 GGG 4042911 ERMS-F9DB-4005021 Information Amendment na US-NINFOC-2200411003294 Fr.3 ROWARD 4002031 ERMS-F9DB-4005031 Information Amendment na PC-NINFOC-2200411003292 Fr.1 ROWARD 4002031 ERMS-F9DB-4005031 Salety Report na PC-NINFOC-220041003292 Fr.1 ROWARD 4002031 ERMS-F9DB-4005031 FINA COLORS (COLORS) Name Amendment na LC-NINFOC-220041003392 Fr.2 ROWARD 4002031 ERMS-F9DB-4005410 Salety Report na US-NINFOC-220051003392 Fr.2 ROWARD 4002031 ROWARD 4002031 ERMS-F9DB-4005410 Salety Report na US-NINFOC-20051003392 Fr.2 ROWARD 4002031 ERMS-F9DB-4005410 ERMS-F9DB-4005410 Salety Report na NIN-NINFOC-20050103392 Fr.2 ROWARD 400200 ROWARD 400200 ERMS-F9DB-4005610 Salety Report na NIN-NINFOC-20050104304 Fr.2 ROWARD 400200 ROWARD 400200 ERMS-F9DB-4003640 ERMS-F9DB-4003640 Salety Report na US-NINFOC-20050104304 Fr.2 ROWARD 400200		Пa	New Protocol; New Hiveshigator	R076477-SCH-705	048	4026257	EDMS-PSDB-4026257	па
Information Ameniment Amen		g	MY-JNJFUC-Z0041103/34 F-3	R076477-SCH-704	049	4042911	EDMS-PSDB-4042911	na
Information Amendment na Printal Cooperation (Amendment) na US_AMISTICO_COODINGSQS Infinial ROPEATY_SCH_701 na 4068548 EDIMS_PSDB-4068319 Printal Cooperation (Amendment) Printal Cooperation (Amendment) na US_AMISTICO_COODINGSQS_FL ROPEATY_SCH_701 na 4068548 EDIMS_PSDB-4068319 Printal Cooperation (Amendment) Printal Cooperation (Amendment) na US_AMISTICO_COODINGSQS_FL ROPEATY_SCH_701 na 4068540 EDIMS_PSDB-4068319 Printal Cooperation (Amendment) na US_AMISTICO_COODINGSQS_FL ROPEATY_SCH_701 055 4068560 COOPERATY_SCH_701 055 4068560 COOPERATY_SCH_701 055 4068560 COOPERATY_SCH_701 055 4068571 EDIMS_FSDB-41199641 056 4068671 EDIMS_FSDB-4119641 056 056 406867 EDIMS_FSDB-41166319 056 406867 056 056 406867 0		g	#l	na	020	4050521	EDMS-PSDB-4050521	Па
Salety Report na PL-NIA-PCX-2004103392 initial RDIAS-PSDB-406319 To RIAS-PSDB-406319 Salety Report na IS-NIA-PCX-2004103392 initial RDIAS-PSDB-406319 To RAME (PROPER) Salety Report na IS-NIA-PCX-2004103392 initial RDIAS-PSDB-406319 To RAME (PROPE) Salety Report na US-NIA-PCX-2004103392 initial RDIAS-PSDB-406319 EDIAS-PSDB-406319 Salety Report na US-NIA-PCX-2004103392 initial RDIAS-PSDB-406319 EDIAS-PSDB-406319 Salety Report na US-NIA-PCX-2004103398 initial RDIAS-PSDB-4063108 EDIAS-PSDB-4063108 Salety Report na US-NIA-PCX-20041200386 F.2 ROTAS-TX-SCH-700 056 409687 EDIAS-PSDB-4063108 Salety Report na US-NIA-PCX-2004120038 F.2 ROTAS-TX-SCH-700 056 409687 EDIAS-PSDB-406316 Salety Report na PCX-NIA-PCX-2004120038 F.2 ROTAS-TX-SCH-700 056 409687 EDIAS-PSDB-406388 Salety Report na PCX-NIA-PCX-2004120030 F.2 ROTAS-TX-SCH-700 056 409687 EDIAS-PSDB-406318		υg	Pharmacology/ I oxicology	B076477-SCH-703	051	4050379	EDMS-PSDB-4050379	na
Salety Report na Pus-Amy-Control Control Cont	_	В	PL-JNJF-UC-ZU04 1Z00Z44 initial	B076477-SCH-701	052	4056138	EDMS-PSDB-4056138	na
FDA Correspondence na List. State Hebort Number Name R076477 SCH-701 G65 4066554 EDMS-PS0B-4053156 FOR STATES AND		g	US-JNJFOC-20050103392 iriiliai	B076477-SCH-701	g	4063491	EDMS-PSDB-4063491	па
Salety Report na CAJNISTOC-2004/120436 F-2 R076477-SCH-306 664 40066534 EDMS-PSDB-4002601 Salety Report na (SAJNISTOC-2004/120436 F-2 R076477-SCH-301 656 4076677 EDMS-PSDB-4002607 Salety Report na US-NINFOC-2005/10538 Initial R076477-SCH-301 656 4092677 EDMS-PSDB-4002607 Salety Report na NiNAPLOC-2006/10538 Initial R076477-SCH-301 658 4098827 EDMS-PSDB-4098677 Salety Report na US-NINAPCC-2006/105084 F-2 R076477-SCH-301 659 4098827 EDMS-PSDB-4098677 Salety Report na US-NINAPCC-2006/105084 F-2 R076477-SCH-301 671 4115429 EDMS-PSDB-4098677 Salety Report na US-NINAPCC-2006/105084 F-2 R076477-SCH-301 671 4115649 EDMS-PSDB-4098677 Salety Report na EDMS-PSDB-400860 66 4098827 EDMS-PSDB-4098677 Salety Report na US-NINAPCC-2006/105084 F-1 R076477-SCH-300 68 420946 EDMS-PSDB-4099677 Salety Report<	$\neg \neg$	ua	Fax: Salety Report Siv USZ	R076477-SCH-701	053	4063195	EDMS-PSDB-4063195	na
Salety Report na VANATOC 2006/10338 Initial R076477-SCH-305 CGF 4070650 EDMS-PSDB-403967 Salety Report na US_MAJECC_2006/10338 Initial R076477-SCH-305 CGE 4092677 EDMS-PSDB-4039687 Salety Report na US_MAJECC_2006/10338 Initial R076477-SCH-305 CGE 4092677 EDMS-PSDB-4039687 Salety Report na US_MAJECC_2006/102338 Initial R076477-SCH-305 CGE 409887 EDMS-PSDB-409887 Salety Report na US_MAJECC_2006/102338 Fri R076477-SCH-305 CGE CDMS-PSDB-409887 FDMS-PSDB-409887 Salety Report na RN-JMLFOC_2006/105338 Fri R076477-SCH-305 CGE 4119644 EDMS-PSDB-409887 Salety Report na RN-JMLFOC_2006/105338 Fri R076477-SCH-305 CGE 4119644 EDMS-PSDB-413747 Salety Report na MY-JMLFOC_2006/105308 Fri R076477-SCH-305 CGE 4119644 EDMS-PSDB-4120498 Salety Report na MY-JMLFOC_2006/105408 Fri R076477-SCH-305 CGE 4119644 EDMS-PSDB-4120498 <td></td> <td>na</td> <td>US-JNJFUC-Z0030 103382 F1</td> <td>R076477-SCH-305</td> <td>054</td> <td>4066354</td> <td>EDMS-PSDB-4066354</td> <td>na</td>		na	US-JNJFUC-Z0030 103382 F1	R076477-SCH-305	054	4066354	EDMS-PSDB-4066354	na
Saliety Report na US-NINI-OC-2005/010538 infail R076477-SCH-305 G66 4092677 EDMS-PSDB-409308B Porticol Amendment na US-NINI-OC-2005/010538 infail H076477-SCH-305 656 409308B EDMS-PSDB-409308B Porticol Amendment na NS-NINI-OC-2004/100538 infail H076477-SCH-305 659 409482D EDMS-PSDB-4094614 Salety Report na NS-NINI-OC-2005/10520 infail H076477-SCH-305 609 409882D EDMS-PSDB-409882D Salety Report na MV-NINI-OC-2005/10538 F-1 H076477-SCH-305 609 419980 EDMS-PSDB-409882D Salety Report na H07-NINI-OC-2005/10538 F-1 H076477-SCH-305 609 419901 EDMS-PSDB-411642D Salety Report na US-NINI-OC-2005/10538 F-1 H076477-SCH-305 605 419901 EDMS-PSDB-411642D Salety Report na US-NINI-OC-2005/10538 F-1 H076477-SCH-305 605 419901 EDMS-PSDB-4116451 Salety Report na US-NINI-OC-2005/10538 F-1 H076477-SCH-305 605 4209464 EDMS-PSDB-4	1	ľa	CA-JNJFOC-2004 I 204-345 F-2	R076477-SCH-301	055	4070650	EDMS-PSDB-4070650	na
Salety Report na Na.JMJFOC.2004120202E F.2 R076477-SCH-704 657 4093088 EDMS-FSDB-4094614 Rottor Report na Nb.JMJFOC.2004120202E F.2 R076477-SCH-704 659 4094614 EDMS-FSDB-4094614 Salety Report na Nb.JMJFOC.200410039E F.2 R076477-SCH-705 650 4098827 EDMS-FSDB-4098827 Salety Report na MY-JMJFOC.20050105402 Initial R076477-SCH-705 650 4098827 EDMS-FSDB-4098827 Salety Report na RO-JMJFOC.20050105305 F.1 R076477-SCH-301 651 4119629 EDMS-FSDB-4119649 Salety Report na RO-JMJFOC.20050105305 F.1 R076477-SCH-305 662 4139644 EDMS-FSDB-412961 Salety Report na MY-JMJFOC.20050105305 F.1 R076477-SCH-305 663 4139644 EDMS-FSDB-412961 Salety Report na MY-JMJFOC.20050105305 F.1 R076477-SCH-305 663 4209442 EDMS-FSDB-421099 Salety Report na US-JMJFOC.20050105395 F.1 R076477-SCH-1009 n65 420496 EDMS-FSDB-421099		Ja J	USSUNAT OCTANGO TO SOCIAL PROPERTY OF THE PROP	R076477-SCH-305	056	4092677	EDMS-PSDB-40926//	na P
Safety Report na Warmingstage 1-2 R076477-SCH-703 0.68 4994614 EDMS-PSDB-4098820 FORMS-PSDB-4098820	┪	ua S	Now Parestratore	R092670-PSY-3004	057	4093088	EDMS-PSDB-4093088	na
Salety Report na INSTANCE COORDINGS F.2 ROTEATT SCH-704 059 4098820 EDMS-PSDB-4198820 Salety Report na INS-AMI-FOC 20050105402 initial ROTEATT SCH-301 061 4116429 EDMS-PSDB-4116920 Salety Report na RO-JANI-FOC 20050105336 F-1 ROTEATT SCH-301 na 4140901 EDMS-PSDB-4116920 Salety Report na IS-SANI-FOC 20050105336 F-1 ROTEATT SCH-301 na 4140901 EDMS-PSDB-4116920 Salety Report na MY-JANI-FOC 20050105336 F-1 ROTEATT SCH-301 na 4140901 EDMS-PSDB-4116944 Salety Report na MY-JANI-FOC 20050105402 F-1 ROTEATT SCH-301 064 4137747 EDMS-PSDB-412091 Salety Report na US-JANI-FOC 20050105402 F-1 ROTEATT SCH-1009 065 4105794 EDMS-PSDB-420942 General Correspondence na US-JANI-FOC 20050304957 Initial ROTEATT SCH-1009 064 4224908 EDMS-PSDB-4205917 Salety Report na INV-JANI-FOC 20050304957 Initial ROTEATT SCH-1009 067 4253965 E	┪	I G	200000	R076477-SCH-703	058	4094614	EDMS-PSUB-4094614	
Salety Report na NCNANTEOC-20050163402 Initial R076477-SCH-305 660 4198827 EDMS-PSDB-4116499 Salety Report na RC-NALFOC-20050163402 Initial R076477-SCH-301 061 4115649 EDMS-PSDB-4116499 Salety Report na Fax. Salety Report Salety Report na R0-NALFOC-2005010538 F-1 R076477-SCH-305 062 4119644 EDMS-PSDB-4119644 Salety Report na RV-NALPOC-2005010538 F-1 R076477-SCH-305 063 4128519 EDMS-PSDB-412964 Salety Report na RV-NALPOC-20050105402 F-1 R076477-SCH-305 063 4128519 EDMS-PSDB-422042 Salety Report na US-NALPOC-20050105402 F-1 R076477-SCH-305 063 420494 EDMS-PSDB-423042 Salety Report na US-NALPOC-20050304857 Initial R076477-SCH-309 065 4204908 EDMS-PSDB-423048 Salety Report na TW-NALPOC-20050304857 Initial R076477-SCH-1009 066 4224908 EDMS-PSDB-425968 Salety Report na MV-NALPOC-2006305249 Initial R076477-SCH-705 <t< td=""><td>1</td><td>2 6</td><td>11.5. IN 1500-2004 100394 F-2</td><td>R076477-SCH-704</td><td>059</td><td>4098820</td><td>EDMS-PSUB-4098820</td><td></td></t<>	1	2 6	11.5. IN 1500-2004 100394 F-2	R076477-SCH-704	059	4098820	EDMS-PSUB-4098820	
Safety Report na ROT-20050201375 Initial ROT-6477-SCH-301 061 4115429 EDMS-PSDB-4140901 Safety Report na Fax. Safety Report 3N 061 ROT-62-20050201375 Initial ROT-676-730 na 4119644 EDMS-PSDB-4119641 Safety Report na US-JMLFOC-2005010538 F-1 ROT-6477-SCH-306 062 4119644 EDMS-PSDB-4119641 Safety Report na MC-JMLFOC-20050105375 F-1 ROT-6477-SCH-300 063 4128519 EDMS-PSDB-4118519 Safety Report na MC-JMLFOC-20050201375 F-1 ROT-6477-SCH-1009 065 4299442 EDMS-PSDB-4210799 Safety Report na US-JMLFOC-20050204957 F-1 ROT-6477-SCH-1009 065 4299442 EDMS-PSDB-4224908 Safety Report na US-JMLFOC-20050304957 F-1 ROT-6477-SCH-1009 066 4224908 EDMS-PSDB-4225891 Safety Report na TW-JMLFOC-20050304957 F-1 ROT-6477-SCH-1009 066 4259408 EDMS-PSDB-422691 Safety Report na MY-JMLFOC-20050402743 for ing ROT-6477-SCH-1009 066 4259682	7	2 6	MAY. IN IECC. 20050105402 Initial	R076477-SCH-305	090	4098827	EDMS-PSDB-4098827	
Safety Report na Fax. Safety Report SN 061 R076477-SCH-305 na 4149901 EUMS-PSDB-4119644 Safety Report na US-JNJFOC-20050105338 F-1 R076477-SCH-305 062 4126549 EDMS-PSDB-4128619 Safety Report na US-JNJFOC-20050105405 F-1 R076477-SCH-305 063 4126549 EDMS-PSDB-4128619 Safety Report na RV-JNJFOC-20050201375 F-1 R076477-SCH-305 063 4137747 EDMS-PSDB-4128619 Safety Report na RV-JNJFOC-20050304957 Initial R076477-SCH-1009 065 4204908 EDMS-PSDB-4224908 Safety Report na US-JNJFOC-20050304957 Initial R076477-SCH-1009 066 4224908 EDMS-PSDB-4224908 Safety Report na US-JNJFOC-20050304957 Initial R076477-SCH-1009 066 4224908 EDMS-PSDB-4224908 Safety Report na MY-JNJFOC-20050304957 Initial R076477-SCH-705 066 4256811 EDMS-PSDB-427898 Safety Report na MY-JNJFOC-20050402753 Initial R0764477-SCH-705 068 4259747 EDMS-PSDB-42	-	2 6	BO. IN IFOC. 20050201375 Initial	R076477-SCH-301	991	4115429	EDMS-PSUB-4 10429	a c
Example of the contraction o	7	2	Eav: Safaty Report SN 061	R076477-SCH-301	g	4140901	EDMS-PSDB-4140901	200
Safety Report na MY-UNIFOC-20050105402 F-1 R076477-SCH-305 063 4128519 EDMS-PSDB-4120319 Safety Report na HO-JNJFOC-20050201375 F-1 R076477-SCH-1001 064 42128519 EDMS-PSDB-420942 Safety Report na US-JNJFOC-20050304957 Initial R076477-SCH-1009 na 4210799 EDMS-PSDB-4210799 Safety Report na US-JNJFOC-20050304957 F-1 R076477-SCH-1009 na 4224908 EDMS-PSDB-4229408 Safety Report na UN-JNJFOC-20050304957 F-1 R076477-SCH-1009 066 4224908 EDMS-PSDB-4234908 Safety Report na IV-JNJFOC-20060306349 initial R076477-SCH-1009 066 4224908 EDMS-PSDB-4234908 Safety Report na IV-JNJFOC-20041204460 F-2 R076477-SCH-705 069 4255811 EDMS-PSDB-425981 Safety Report na INL-INJFOC-2005042753 Initial R076477-SCH-705 070 4267510 EDMS-PSDB-428984 Safety Report na US-JNJFOC-20050105338 F-2 R076477-SCH-705 071 4279741 EDMS-PSDB-428961	7	2	I.S. IN IFOC. 20050105338 F-1	R076477-SCH-305	82	4119644	EUMS-PSUB-41 3044	
Safety Report na MP-JNLFOC-20050201375 F-1 R076477-SCH-301 064 4137747 EDMS-PSDB-412/747 Safety Report na US-JNLFOC-20050204957 Initial R076477-SCH-1009 065 4204942 EDMS-PSDB-420799 Safety Report na US-JNLFOC-20050304957 Initial R076477-SCH-1009 na 4210799 EDMS-PSDB-42079B Safety Report na US-JNLFOC-20050304957 F-1 R076477-SCH-1009 na 4224908 EDMS-PSDB-42079B Safety Report na US-JNLFOC-20050304957 F-1 R076477-SCH-1009 na 4224908 EDMS-PSDB-42290B Safety Report na TW-JNLFOC-20050304967 F-1 R076477-SCH-105 na 4255811 EDMS-PSDB-425981 Safety Report na MY-JNLFOC-200504120460 F-1 R076477-SCH-105 na 4255811 EDMS-PSDB-425982 Safety Report na NI-N-MAPOC-20050412753 Initial PALIOROS-SCH-1011 070 427894 EDMS-PSDB-4279747 Safety Report na US-JNJFOC-200504102753 Initial PALIOROS-SCH-1011 070 4279747 EDMS-PSDB-4279747 </td <td>┰</td> <td>2 2</td> <td>MV- IN JEVC-20050105402 F-1</td> <td>R076477-SCH-305</td> <td>8</td> <td>4128519</td> <td>EUMS-PSUB-4128519</td> <td></td>	┰	2 2	MV- IN JEVC-20050105402 F-1	R076477-SCH-305	8	4128519	EUMS-PSUB-4128519	
Safety Report na US_JUNIFOC_20050304957 Initial R076477_SCH+1009 065 4206442 EDMS-PSDB-4207492 Safety Report na US_JUNIFOC_20050304957 Initial R076477_SCH+1009 na 4210799 EDMS-PSDB-4224908 Safety Report na US_JUNIFOC_20050304957 F-1 R076477_SCH+1009 066 4223965 EDMS-PSDB-4223965 Safety Report na TW_JUNIFOC_20041204460 F-2 R076477_SCH+705 068 4255811 EDMS-PSDB-4253955 Safety Report na MY_JUNIFOC_20041204460 F-2 R076477_SCH+705 068 4255812 EDMS-PSDB-425982 Safety Report na NL_JUNIFOC_20041204460 F-2 R076477_SCH+705 069 425581 EDMS-PSDB-427974 Safety Report na NL_JUNIFOC_2005402773 Initial PALIOROS-SCH+1011 na 427894 EDMS-PSDB-427974 Safety Report na US_JUNIFOC_2005402753 Initial R076477-SCH+305 071 4279747 EDMS-PSDB-4279747 Safety Report na US_JUNIFOC_2005402753 Initial R076477-SCH+305 077 4279747 EDMS-PSDB-	_	<u> </u>	BO. IN IFOC. 20050201375 F-1	R076477-SCH-301	\dashv	4137747	EDMS-PSDB-413/74/	200
Satety Report na Fax. Safety Report SN 065 R076477-SCH-1009 na 4210799 EDMS-PSDB-4210789 Safety Report na US-JN/FOC-20060304957 F-1 R076477-SCH-1009 066 4224908 EDMS-PSDB-4224908 Safety Report na TW-JNJFOC-20060305349 Initial R076477-SCH-1009 066 4225401 EDMS-PSDB-425891 Safety Report na MY-JNJFOC-20041204460 F-1 R076477-SCH-705 068 4255811 EDMS-PSDB-425891 Safety Report na MY-JNJFOC-20041204460 F-2 R076477-SCH-705 069 4256810 EDMS-PSDB-425891 Safety Report na NL-JNJFOC-20050402753 Initial PALIOROS-SCH-1011 070 4267510 EDMS-PSDB-4279747 Safety Report na US-JNJFOC-2005105338 F-2 R076477-SCH-705 072 4279747 EDMS-PSDB-4279761 Safety Report na US-JNJFOC-20041106754 F-4 R076477-SCH-705 072 4279761 EDMS-PSDB-4279761 Safety Report na NL-JNJFOC-20041100394 F-3 R076477-SCH-705 073 4279761 EDMS-PSDB-4279761	_	2 2	115.1N JEOC-20050304957 Initial	H076477-SCH-1009	-	4209442	EDMS-PSDB-4209442	
Safety Report na US_JNJFOC-20050304957 F-1 R076477-SCH-1009 066 4224908 EDMS-PSDB-423355 Safety Report na TW-JNJFOC-20050305349 Initial R076477-SCH-705 067 4255811 EDMS-PSDB-4255811 Safety Report na MY-JNJFOC-20041204460 F-2 R076477-SCH-705 069 4255812 EDMS-PSDB-4267510 Safety Report na MV-JNJFOC-200402753 Initial PALIOROS-SCH-1011 070 425684 EDMS-PSDB-4276710 Safety Report na NL-JNJFOC-20050402753 Initial PALIOROS-SCH-1011 070 4278974 EDMS-PSDB-4279747 Safety Report na US-JNJFOC-200504105738 F-2 R076477-SCH-705 072 427977 EDMS-PSDB-4279761 Safety Report na US-JNJFOC-2005041105754 F-4 R076477-SCH-704 073 4279761 EDMS-PSDB-4279761 Safety Report na US-JNJFOC-2005041100394 F-3 R076477-SCH-704 073 4279761 EDMS-PSDB-4279761 Safety Report na US-JNJFOC-200504100394 F-3 R076477-SCH-704 073 4279761 EDMS-PSDB-427976	-	+	Fax: Safety Report SN 065	R076477-SCH-1009	4	4210799	FDMS-PSDB-4210799	
Safety Report na TW-JNJFOC-20060305349 Initial R076477-SCH-305 067 423390 EDMS-P204-2030 Safety Report na MY-JNJFOC-20041204460 F-2 R076477-SCH-705 068 4256811 EDMS-PSDB-4256811 Safety Report na MY-JNJFOC-20041204460 F-2 R076477-SCH-705 069 4256811 EDMS-PSDB-4267510 Safety Report na NL-JNJFOC-20050402753 Initial PALIOROS-SCH-1011 070 427671 EDMS-PSDB-4276710 Safety Report na US-JNJFOC-200504102753 Initial PALIOROS-SCH-1011 070 427874 EDMS-PSDB-4279747 Safety Report na US-JNJFOC-200504105338 F-2 R076477-SCH-705 072 4279761 EDMS-PSDB-4279761 Safety Report na US-JNJFOC-200504110574 F-4 R076477-SCH-704 073 4279761 EDMS-PSDB-4279761 Safety Report na US-JNJFOC-2005041100394 F-3 R076477-SCH-704 073 4279761 EDMS-PSDB-4279761 Safety Report na NL-JNJFOC-200504100394 F-3 PALIOROS-SCH-1011 074 4287661 EDMS-PSDB-427976	+	\downarrow	US-JNJFOC-20050304957 F-1	R076477-SCH-1009	+	4224908	EDMS-1309-4224300	
Safety Report na MY-JNJFOC-20041204460 F-1 R076477-SCH-705 068 425981 FDMS-PSDB-4259582 Safety Report na MY-JNJFOC-20041204460 F-2 R076477-SCH-705 069 4259582 EDMS-PSDB-4259582 Safety Report na NI-JNJFOC-20050402753 Initial PALIOROS-SCH-1011 na 4278949 EDMS-PSDB-4279747 Safety Report na US-JNJFOC-20050105338 F-2 R076477-SCH-705 071 4279747 EDMS-PSDB-4279747 Safety Report na US-JNJFOC-20050105338 F-2 R076477-SCH-705 072 4279747 EDMS-PSDB-4279761 Safety Report na US-JNJFOC-20041105754 F-4 R076477-SCH-704 073 4279122 EDMS-PSDB-4279761 Safety Report na US-JNJFOC-20041100394 F-3 R076477-SCH-704 073 4279122 EDMS-PSDB-4279761 Safety Report na NL-JNJFOC-200504120735 F-1 PALIOROS-SCH-1011 074 4287661 EDMS-PSDB-4279122 Safety Report na NL-JNJFOC-20050402753 F-1 PALIOROS-SCH-1011 075 4322913 EDMS-PSDB-4272913	T	60	TWIN.JFOC-20050305349 Initial	R076477-SCH-305	ĝ	4233955	CDM3-1-300-4253333	
Safety Report na MY-JNJFOC-20041204460 F-2 R076477-SCH-705 069 4259502 EDMS-PSDB-4267510 Safety Report na NL-JNJFOC-20050402753 Initial PALIOROS-SCH-1011 na 4267510 EDMS-PSDB-4277510 Safety Report na US-JNJFOC-20050105338 F-2 PALIOROS-SCH-1011 na 427894 EDMS-PSDB-4279747 Safety Report na US-JNJFOC-20050105338 F-2 R076477-SCH-705 072 4279761 EDMS-PSDB-4279761 Safety Report na US-JNJFOC-2004110574 F-4 R076477-SCH-704 073 4279761 EDMS-PSDB-4279761 Safety Report na US-JNJFOC-20041100394 F-3 R076477-SCH-704 073 4279122 EDMS-PSDB-4279161 Safety Report na US-JNJFOC-2005402753 F-1 R076477-SCH-704 073 4287661 EDMS-PSDB-4287661 Safety Report na NL-JNJFOC-20050402753 F-1 PALIOROS-SCH-1011 074 4287661 EDMS-PSDB-428769 IND Amendment na Neclassification of Indicated Reports na R075 4322769 EDMS-PSDB-4322769 <td>┱</td> <td>2</td> <td>MY-JNJFOC-20041204460 F-1</td> <td>R076477-SCH-705</td> <td>80</td> <td>4255811</td> <td>COMOS-PODDS-42005</td> <td></td>	┱	2	MY-JNJFOC-20041204460 F-1	R076477-SCH-705	80	4255811	COMOS-PODDS-42005	
Safety Report na NL-JMJFOC-20050402753 Initial PALIOROS-SCH-1011 070 4267510 EDMS-PSDB 4278984 Safety Report na NL-JMJFOC-20050105338 F-2 PALIOROS-SCH-1011 na 4278934 EDMS-PSDB 42789747 Safety Report na US-JMJFOC-20050105338 F-2 R076477-SCH-305 071 4279747 EDMS-PSDB 4279761 Safety Report na WY-JMJFOC-20041105754 F-4 R076477-SCH-705 072 4279761 EDMS-PSDB 4279122 Safety Report na US-JMJFOC-20041100394 F-3 R076477-SCH-704 073 4279122 EDMS-PSDB 4287661 Safety Report na NL-JMJFOC-20050402753 F-1 PALIOROS-SCH-1011 074 4287661 EDMS-PSDB 4222913 IND Amendment na Reclassification of IND Safety Reports na 075 4322769 EDMS-PSDB 4322769	+	2 0	MY-, IN JEOC-20041204460 F-2	R076477-SCH-705	4	4259582	EUMO-LODGE-ESSON	
Satety Report na 427894 EDMS-PSDB-427894 EDMS-PSDB-427894 General Correspondence na US-JNJFOC-20050105338 F-2 R076477-SCH-305 071 4279747 EDMS-PSDB-4279747 Safety Report na WY-JNJFOC-20041105754 F-4 R076477-SCH-705 072 4279761 EDMS-PSDB-4279761 Safety Report na US-JNJFOC-20041100394 F-3 R076477-SCH-704 073 4279122 EDMS-PSDB-4287661 Safety Report na NL-JNJFOC-20050402753 F-1 PALIOROS-SCH-1011 074 4287661 EDMS-PSDB-4287661 Safety Report na NL-JNJFOC-20050402753 F-1 na 075 4322913 EDMS-PSDB-4322913 IND Amendment na Reclassification of IND Safety Reports R075 4322769 EDMS-PSDB-4322769	7		NI - IN IFOC. 20050402753 Initial	PALIOROS-SCH-101	4	4267510	EDMS-PSDB-4267510	
General Cortespondence na US_UNIFOC-20050105338 F-2 R076477-SCH-305 071 4279747 EUMS-PSDB-4279761 Safety Report na US_UNIFOC-20040106754 F-4 R076477-SCH-705 072 4279761 EDMS-PSDB-4279161 Safety Report na US_UNIFOC-20041100394 F-3 R076477-SCH-704 073 4279122 EDMS-PSDB-428761 Safety Report na NL-JUNIFOC-20050402753 F-1 PALIOROS-SCH-1011 074 4287661 EDMS-PSDB-422913 IND Amendment na Reclassification of IND Safety Reports na 075 4322913 EDMS-PSDB-4322769 IND Amendment na New Protocol New Investigator R092670-PSV-3003 076 4322769 EDMS-PSDB-4322769	\neg	+	Fax: Safety Report SN 070	PALIOROS-SCH-101	_	4278984	EUMS-PSD8-42/6364	
Safety Report na MY-JNJFOC-20041105754 F-4 R076477-SCH-705 072 4279761 EDMS-FSDB-4279122 Safety Report na US-JNJFOC-20041100394 F-3 R076477-SCH-704 073 4279122 EDMS-PSDB-4279122 Safety Report na NL-JNJFOC-20050402753 F-1 PALIOROS-SCH-1011 074 4287661 EDMS-PSDB-4287961 Safety Report na NL-JNJFOC-20050402753 F-1 na 075 4322913 EDMS-PSDB-4322913 IND Amendment na Reclassification of IND Safety Reports R092670-PSV-3003 076 4322769 EDMS-PSDB-4322769	_	+	US-JNJFOC-20050105338 F-2	R076477-SCH-305	4	4279747	EUMS-PSUB-42/9/4/	1
Safety Report na US-JNJFOC-20041100394 F-3 R076477-SCH-704 073 4279122 EDMS-FSDB-4273122 Safety Report na US-JNJFOC-20050402753 F-1 PALIOROS-SCH-1011 074 4287661 EDMS-FSDB-4287661 Safety Report na NL-JNJFOC-20050402753 F-1 na 075 4322913 EDMS-FSDB-4322913 IND Amendment na Reclassification of IND Safety Reports R092670-PSY-3003 076 4322769 EDMS-PSDB-4322769	_	2 6	MYIN.IFOC-20041105754 F-4	R076477-SCH-705	\dashv	4279761	EUMV-PSUB-42/9/0	
Satety Report na NL-JNJFOC-20050402753 F-1 PALIOROS-SCH-1011 074 428/661 EUMO-FSDB-4227031 Safety Report na 075 4322913 EDMS-FSDB-4322913 IND Amendment na Profacol: New Investigator R092670-PSV-3003 076 4322769 EDMS-PSDB-4322769	1	5 6	HS-INJFOC-20041100394 F-3	R076477-SCH-704	\perp	4279122	EUMS-PSUB-42/9126	
Safety Report na Reclassification of IND Safety Reports na Now Protocol: New Investigation	_	8 6	NI - IN JEOC-20050402753 F-1	PALIOROS-SCH-101		4287661	EDMS-PSUB-428/80	
IND Amendment	+	5	Beclassification of IND Safety Reports	na	-	4322913	EUMS-F5DB-4322910	
	_	2 2	Mon. Drotocol: New Povestinator	R092670-PSY-3003	Ц	4322769	EDMS-PSDB-432276	J I III

		Dad S		Protocol #	SN# Sec	Sequence #	Hyperlink	
Date	Submission Type	Contact	Control of the Contro	R092670-PSY-3004	7.70	4325611	EDMS-PSDB-4325611	na
35	Protocol Amendment		New Investigators	B092670-PSY-3001	078	4329282	EDMS-PSDB-4329282	па
Т	Protocol Amendment			R076477.SCH-1009	620	4343153	EDMS-PSDB-4343153	na
1	Safety Report	па	US-JNJFOC-20050502821 Initial	B076477-SCH-1009	E C	4348879	EDMS-PSDB-4348879	na
1	FDA Correspondence	na		D076477,SCH-705	080	4354981	EDMS-PSDB-4354981	na
Т	Safety Report	Па		B076477-SCH-301	081	4362170	EDMS-PSDB-4362170	na
1	Safety Report	na	- 1	B076477-SCH-301	082	4381574	EDMS-PSDB-4381574	na
	Safety Report		IN-JNJFOC-20050503897 F-1	B002670-PSY-3003	083	4403047	EDMS-PSDB-1103047	
	Information Amendment	па	CM&C	60	084	4411495	EDMS-PSDB-4411495	na en
6/13/2005	General Correspondence	ทล	Request for Review of Drug Product Registration Stability	9				
			Projectol	R092670-PSY-3001	085	4411736	EDMS-PSDB-4411736	
6/14/2005	Information Amendment	na	Change in Protocol	R092670-PSY-3004	980	4411745	EDMS-PSDB-4411745	
6/14/2005	Information Amendment	na	Change III Fluidou	R092670-PSY-3005	087	4416120	EDMS-PSDB-4416120	
6/15/2005	Information Amendment	па	New Protocol; New III Vesugators	R092670-PSY-1001	880	4414564	EDMS-PSDB-4414564	
6/15/2005	Information Amendment	па	New Protocol; New Investigators	PALIOROS-P01-1011	680	4421835	EDMS-PSDB-4421865	
6/15/2005	Safety Report	na	NL-JNJFUC-ZU00040Z703 F-Z	R076477-SCH-301	060	4424386	EDMS-PSDB-4424386	
6/16/2005	Safety Report	na	US-JNJFUC-20U41201617 F-1	R076477-SCH-301	160	4431011	EDMS-PSDB-4431011	пā
6/17/2005	Safety Report	na	US-JNJFOC-Z0050 10558Z T-5	R076477-SCH-705	092	4441911	EDMS-PSDB-4441911	Ja Ja
6/23/2005	Safety Report	na	US-JNJFUC-ZUUSUSUSUS IIIIIIIII	R092670-PSY-1004	093	4460769	EDMS-PSDB-4460769	
6/28/2005	Protocol Amendment	na	New Protocol; New Investigators	R092670-PSY-1004	094	4465586	EDMS-PSDB-4465586	
6/29/2005	Protocol Amendment	na	New Investigators	R076477-SCH-1009	960	4477198	EDMS-PSDB-4477198	
7/1/2005	Safety Report	Па	US-JNJFOC-20050304957 F-2	B076477-SCH-301	960	4482015	EDMS-PSDB-4482015	
7/6/2005	Safety Report	na	IN-JNJFOC-200503897 F-2	B076477-SCH-705	760	4484198	EDMS-PSDB-4484198	na
7/6/2005	Safety Report	na	US-JNJFOC-20050e03e07 r-1	R076477-SCH-705	860	4520333	EDMS-PSDB-4520333	
7/15/2005	Safety Report	na	MY-JNJFOC-20041204460 F-4	60	660	4525548	EDMS-PSDB-4525548	
7/19/2005	IND Amendment	па	Investigator's Brochure: Agenda	R076477-SCH-705	8	4529100	EDMS-PSDB-4529100	
7/20/2005	Safety Report	Za	MY-JNJFOC-Z0041Z04400 F-3	eu.	101	4531527	EDMS-PSDB-4531527	na
7/21/2005	Information Amendment	na	CM&C	B092670-PSY-1002	102	4544136	EDMS-PSDB-4544136	
7/26/2005	Protocol Amendment	па	New Protocol; New Investigators	0	103	4565568	EDMS-PSDB-4565568	en en
8/1/2005	IND Amendment	na L	Request for Review of Revised Drug Product negligible and the County Negligible an	1				
	_		Stability Florous	na	104	4574605	EDMS-PSDB-4574605	
8/5/2005	Annual Report	па	Reporting Period, 00/0/04 - 00/00/05	B092670	105	4586146	EDMS-PSDB-4586146	
8/5/2005		па	New Protocol, New Hilly Solidated Draw Droduction Benjetration	-	na	4692158	EDMS-PSDB-4692158	na 3
9/9/2005	Record of Contact	<u> </u>	FDA Acceptance of Afficience Drug 1 locacion 1 cgreens Stability Protocol for F013				2040374 00000:00:00	
	Т	2 00	Fax: Report to FDA from Sterling IRB	R092670-PSY-3004	na	4758438	EUMS-PSUB-4/30430	91.00
9/26/2005	Record of Contact	9/26/2005	+	na	e E	4821292	EUMS-PSUB-4621232	
			ILC	na	99	4762944	EDMS-PSDB-4762944	4 na
9/29/2005	_	g	J. Manyhowicz is Now military Contact	R092670-PSY-1004	107	4764829	EDMS-PSDB-4764829	
9/30/2005	_	EE .	New Investigators	R092670-PSY-3004		4771325	EDMS-PSDB-4771325	
9/30/2005		uga S	INEW IIIVESINGATOR STAFF.9	R076477-SCH-301		4867147	EDMS-PSDB-486/14	
10/26/2005	_	E S	CA IN IEOC. 20054101542 Initial	R076477-SCH-705	110	4925304	EDMS-PSDB-4925304	
11/11/2005	Safety Report	Ig	CA-31/01-CO-20031-301512 Filling	R076477-SCH-705	111	4951293	EDMS-PSDB-4951293	
11/21/2005	Safety Report	2 2	Regisest for Review of Revised Drug Product Registration	na	112	4966845	EDMS-PSDB-4966845	na L
11/29/2005	IND Amenomen	<u></u>	Stability Protocol			00400	EDMC_PCDB_5019672	na o
12/20/2005	S Record of Contact	12/7/2005	+	na B	na	2/06/12	EDINO-1 SEE-SOLSS	
			Original Medicing	e e	113	5029714	EDMS-PSDB-5029714	
12/21/2005		Ja	Minutes of the 12/703 Elid of Figure 2 moderns	R076477-SCH-705	114	5030729	EDMS-PSDB-5030729	
12/22/2005		na	CA-JNJFOC-2003110131217-2	R076477-SCH-705	_	5040289	EDMS-PSDB-5040289	
12/29/2005		na	CA-JNJFUC-ZUUSI INISIZI F-S	R092670-PSY-3002	116	5131076	EDMS-PSDB-5131076	
2/2/2006		na	New Protocol; INEW IIIVESTINGATORS	R092670-PSY-3004	L	5205422	EDMS-PSDB-520542	2 na
2/23/2006		na	New Investigators		1			

Dot	Submission Type	Date of	Description	Protectol #	# # 80	EDMS or Sequence #	Hyperlink	Gateway Receipt
3/6/2006	General Correspondence	na	IRB Waiver Request	na	118	5248420	EDMS-PSDB-5248420	,
3/24/2006	Safety Report	na	IN-JNJFOC-20060205306 7/15 Day Initial	R076477-SCH-701	119	5324478	EDMS-PSDB-5324478	na
3/24/2006	General Correspondence	na	Fax: IN-JNJFOC-20060205306 7/15 Day Initial	R076477-SCH-701	119	5358805	EDMS-PSDB-5358805	
3/27/2006	Information Amendment	na	Clinical: Statistical Analysis Plan for R096270-PSY-3004	R092670-PSY-3004	120	5330146	EDMS-PSDB-5330146	
4/3/2006	General Correspondence	na	Fax: IN-JNJFOC-20060205306 7/15 Day F-1	R076477-SCH-701	121	5352966	EDMS-PSDB-5352966	
8/06/2008	FDA Correspondence	60	I etter: IRB Waiver Request Granted (S-117)	R092670-PSY-3004	na	5546925	EDMS-PSDB-5546925	na
5/26/2008	FDA Correspondence	Da l	Email/Attachment: IRB Wavier Request Granted (S-117)	R092670-PSY-3004	ηa	5545009	EDMS-PSDB-5545009	na
8/20/2008	IND Amendment	22	Protocol R092670-PSY-3003 Medication Kit Error	R092670-PSY-3003	122	5593354	EDMS-PSDB-5593354	na
8/28/2008	Information Amendment	eu	Clinical: Statistical Analysis Plan for R096270-PSY-3003	R092670-PSY-3003	123	5617192	EDMS-PSDB-5617192	па
6/27/2006	Becord of Contact	6/23/2006	DSI Notification of Study Compliance Deficiencies	na	na	6380254	EDMS-PSD8-6380254	na
7/11/2006	Information Amendment	na	Clinical	R092670-PSY-3001;	124	5645851	EDMS-PSDB-5845851	na
			-	R092670-PSY-3002;				
				R092670-PSY-1004	10,	100001	20000 BOOD 0100	
7/12/2006	Safety Report	na	IN-JNJFOC-20060205306 F-2	R076477-SCH-701	125	5662755	EUMS-PSUB-5662755	E S
7/17/2006		na n	Email/Attachment: Poland Investigator Site Audit with CL for SN 124	H0926/0-PSY-3001; R092670-PSY-3002; R092670-PSY-1004	g	5/04533	EUMS-F3D8-3704933	
7/21/200E	EDA Correspondence	PO C	Email: SAP for R092670-PSY-3003	R092670-PSY-3003	g	5714883	EDMS-PSDB-5714883	na
7/31/2006	FDA Correspondence	g	Email: FDA Response to Statistical Questions from 6/26/06	Па	na	6033820	EDMS-PSDB-6033820	na
8/10/2006	IND Amendment	na	Investigator's Brochure: Addendum	na	126	5755623	EDMS-PSDB-5755623	Па
8/14/2006	IND Amendment	na	Gen Corr. Request for Type B Pre-Phase 3 Meeting	na	127	5765064	EDMS-PSDB-5765064	P.
8/17/2006	FDA Correspondence	па		na	Па	5799979	EDMS-PSDB-5799979	na
9/1/2006	IND Amendment	na	Gen Corr: Request for Type C Meeting	na	128	5827016	EDMS-PSDB-5827016	na
9/6/2006	Safety Report	na	IN-JNJFOC-20060805629 Initial	R076477-BIM-3002	129	5838723	EDMS-PSDB-5838723	na
9/12/2006	FDA Correspondence	na	Email/Attachment: Meeting Request	na	na	5922314	EDMS-PSDB-5922314	na
9/18/2006	Annual Report	na	Reporting Period: 06/07/05 - 06/06/06	na	130	5868840	EDMS-PSDB-5868840	na
9/20/2006	FDA Correspondence	na	Email: Electronic Submissions	na	g	5922383	EDMS-PSDB-5922383	na
9/21/2006	General Correspondence	па	Request for Special Protocol Assessment	R076477-SCA-3003	5	5895887	EDMS-PSDB-5895887	na
9/22/2006	FDA Correspondence	na	Email: Meeting Granted	na	ē	5922505	EDMS-PSD8-5922505	na
9/22/2006	FDA Correspondence	na	Email: Bipolar & Schizophrenia Meeting Requests	na	ng	5922449	EDMS-PSDB-5922449	na
9/25/2006	FDA Correspondence	na	Email: Bipolar & Schizophrenia Meeting Requests	กล	E E	5922559	EUMS-PSUB-5922559	na
9/26/2006	FDA Correspondence	na	Email: Meeting Granted (12:08pm)	na	g	5922643	EDMS-PSDB-5922643	na
9/26/2006	FDA Correspondence	na	Email: Meeting Granted (3:22pm)	na	g	5922614	EDMS-PSDB-5922614	na
9/26/2006	Safety Report	na	IN-JNJFOC-20060805629 F-1	R076477-BIM-3002	132	5908836	EDMS-PSDB-5908836	na
10/6/2006	-	na	eCTD Submission Conversion	na	133	0000	GW eCTD TOC	na
10/11/2006		па	IN-JNJFOC-20060205306 7/15 Day F-3	H076477-SCH-701	छ	0134	GW eCID IOC	na
10/18/2006	_	na	IN-JNJFOC-20060805629 F-2	R076477-BIM-3002	135	0135	GW eCID IOC	na
10/27/2006	FDA Correspondence	na	Email: Transfer of Regulatory Responsibility	na	g	6027729	EUMS-PSUB-6027739	na
11/3/2006	FDA Correspondence	22	Letter: RFI in Response to 9/21/06 Request for Special	na	e e	6058010	EUMS-PSDB-6058010	g
44/0000	Information Amondmont	50	Cloical: Statistical Analysis Plan for PSV-3001	R092670.PSY-3001	136	0136	GW eCTD TOC	na
0007/0/11	Control Control Control	D	Display Div For 19/11/06 Typo C Mosting	60	137	0137	GW eCTD TOC	ВП
11/9/2006	_	n d	Intentity right conception type of meeting	D076477 BIM-3009	200	0138	GW OCTO TOC	60
11/2//2000	Salety Report	110	III-JINJI OC-EOUGOGOOGE F-5	2000-14110-14110	3 8	6159463	FDMS-PSDB-6159463	80
12/4/2006	FDA Comespondence	Z 2	Email/Attachment: N136 State Commonle	R092670-PSY-3001	2	6163931	EDMS-PSDB-6163931	na
12/0/2008	Sofoty Bonort	5 6	SE. IN IEOC. 20061005337	R092670-PSY-3002	139	0139	GW eCTD TOC	na
12/18/2006	-	8	Multiple (9)	Multiple	140	0140	GW eCTD TOC	na
12/18/2006	_	na	DE-JNJFOC-20061200532 I	R076477-BIM-3004	141	0141	GW eCTD TOC	na
12/19/2006	_	па	Clinical: Statistical Analysis Plan for R092670-PSY-3001	R092670-PSY-3001	142	0142	GW eCTD TOC	na
12/21/2006	_	98		па	В	6218032	EDMS-PSDB-6218032	na
10/00/20/08	19/99/9006 Protocol Amendment	2	Sychiatry Products on 12/11/06 Statistical Analysis Plan for R092670-PSY-3005	R092670-PSY-3005	143	0143	GW eCTD TOC	na
16/66/6000	ורוסוטכטו איוופווטוופויו	- 2		1				

144 0144 EDMS-PSDB-624865	Submission Type	Confact	Description	#	331	Sequence #	Hyperlink	
The control of the	ant	па	Minutes of December 11, 2006 Type C Meeting	Пã	144	0144	GW eCTD TOC	na
Telecontrol	ondence	na	Letter: Official Meeting Minutes from 12/11/06 Telecon	na	na	6248267	EDMS-PSDB-6248267	па
New Propose	ondence	na	Email/Attachment: Official Meeting Minutes from 12/11/06 Telecon	na	па	6241885	EDMS-PSDB-6241885	กล
Progression of Translatterherier Meeting Becuest, Experience and Final-Mutachment Meeting Sequential Programmer and Final-Mutachment Meeting Sequential Programmer Annual Meeting Sequential Progr	endment	na	New Protocol	R092670-PSY-3007	145	0145	GW eCITD TOC	na
Equiple Total Multachment Program Patrick Patric	respondence	na	Request for Type B Pre-Phase 3 Meeting	na	146	0146	GW eCTD TOC	na
The control of the	ondence	na	Email/Altachment: Meeting Request, Paliperidone Palmitate Bipolar Development Program	na	E	6264901	EDMS-PSDB-6264901	na
Providence Tel Charle Ch	ondence	na	Email: Plan to Stop Study R092670-PSY-3001	R092670-PSY-3001	па	6308521	EDMS-PSDB-6308521	na
Special Content	ontact	na	FDA Div. Of Scientific Affairs: Telephone Contact Memo Between FDA and Local Trial Manager in Global Clinical Operations	R092670-PSY-3001	В	6360613	EDMS-PSDB-6360613	กล
Acadysis Pen Let Protocol R02670-PSY-3001 147 0147	respondence	a	Response to RFI: Copy of Protocol R092670-PSY-3001	R092670-PSY-3001	па	6324934	EDMS-PSDB-6324934	na
Part	nendment	Па	Notification of PSY-3001 Study Termination Due to Efficacy, Change in Protocol R092670-PSY-3001; Final Statistical Analysis Plan for R092670-PSY-3001	R092670-PSY-3001	147	0147	GW eCTD TOC	na
Hear Protoco, New Investigators Hogogrop-PSY-3006 149 01450 GW eCTD TOC	rrespondence	na		R092670-PSY-3007	148	0148	GW eCTD TOC	na
The control of the	nendment	na	New Protocol; New Investigators	R092670-PSY-3006	149	0149	GW eCTD TOC	na
Specification Colorate Protection Rogestro-PSY-3001 Flogs	fment	กล	IRB Waiver Request	R092670-PSY-3006	150	0150	GW eCTD TOC	na
Size Closure: Net Closure: Ne	Contact	2/6/2007	GCP Violations at Dr. Chaganiti's Site Under Protocol R092670-PSY-3001	R092670-PSY-3001	па	6383191	EDMS-PSDB-6383191	na
spondence na HS-NNIPCOExport/2008 18 initial ROYATY-SCA.3002 152 O152 GW eCTD TOC na Request for a Type B, Pe-NDA Meeting na H54 6416129 GW eCTD TOC na FaxAffarchment: 716 Day Salety Report (K.Kedrow) na H54 6416129 EDMS-PS0B-6451835 na FaxAffarchment: 716 Day Salety Report (K.Kedrow) na H54 6416129 EDMS-PS0B-6451835 ndence na LS-NINFOC-2007/2004825 Initial 1710 Day (Depart) ROYATY-2004 Na GW eCTD TOC na US-NINFOC-2007/2004825 Initial ROYATY-2004 Na GS-SIGN GRAPE (DAS-PS)B-642812 na LS-NINFOC-2007/2004825 Initial ROYATY-2004 Na GW eCTD TOC na LS-NINFOC-2007/2004822 Initial ROYATY-2004 Na GW eCTD TOC na LS-NINFOC-2007/2004822 Initial ROYATY-2004 Na Na na US-NINFOC-2007/2004822 Initial ROYATY-2004 Na Na na US-NINFOC-2007/2004822 Initial ROYATY-2004 Na Na na	orrespondence	na	Response to RFI from DSI: Protocol R092670-PSY-3001 Site Closure: MedClin Research, Inc.	R092670-PSY-3001	151	0151	GW eCTD TOC	กล
Page	ort	па	US-JNJFOC020070201813 Initial	R076477-SCA-3002	152	0152	GW eCTD TOC	na
Package Pack	rrespondence	Па	Request for a Type B, Pre-NDA Meeting	na	153	0153	GW eCTD TOC	na
The control of the	spondence	an S	Fax/Attachment: 7/15 Day Safety Report (K.Kiedrow)	na	154	6416129	EDMS-PSDB-6416129	na
na Email: 4/18/07 Type B Meeting Request Granted na 6429676 EDMS-PSDB-6429676 na US_NNIFOC_2000204832 Initial RO76477-SCA-3001 155 GMS-BSDB-6446121 na Letter: IRB Waiver Granted for 26/07 SN 150 Submission R092670-PSY-3006 na 6452312 EDMS-PSDB-6452312 na Letter: IRB Waiver Granted for 26/07 SN 150 Submission R092670-PSY-3006 na 6452312 EDMS-PSDB-6452312 na Letter: IRB Waiver Granted for 1731/07 SN 148 Submission R092670-PSY-3006 na 652312 EDMS-PSDB-6452312 na US-JNJFOC-20070204832 F-1 R076477-SCA-3001 157 0156 GW eCTD TOC dinent na US-JNJFOC-20070204832 F-1 R076477-SCA-3001 158 GW eCTD TOC dinent na US-JNJFOC-20070204832 F-1 R076477-SCA-3001 157 0156 GW eCTD TOC dinent na LOS-NATO-C-20070204832 F-2 R076477-SCA-3001 160 0166 GW eCTD TOC dinent na LOS-NATO-C-20070204832 F-2 R076477-SCA-3001 161 0167 GW eCTD TOC </td <td>application of</td> <td>na R</td> <td>US-JNJFOC-20070203055 Initial 7/15 Day Report</td> <td>R076477-BIM-3004</td> <td>2 2</td> <td>154</td> <td>GW eCTD TOC</td> <td>Da Ca</td>	application of	na R	US-JNJFOC-20070203055 Initial 7/15 Day Report	R076477-BIM-3004	2 2	154	GW eCTD TOC	Da Ca
na US_NNJFOC_20070204832 Initial Ho76477-SCA-3001 155 GW eCTD TOC na Fax: US_NNJFOC_20070204832 Initial R076477-SCA-3001 155 6446121 EDMS-PSDB-645312 ndence na Letter; IRB Waiver Granted for 1/31/07 SN 148 Submission R092670-PSY-3007 na 6526103 EDMS-PSDB-645312 ndence na US_NNJFOC_20070203055 F-1 R076477-SIN-300 156 GW eCTD TOC ndent na US_NNJFOC_20070204832 F-1 R076477-SCA-3001 157 GW eCTD TOC dment na US_NNJFOC_20070204832 F-2 R076477-SCA-3001 158 0159 GW eCTD TOC dment na US_NNJFOC_20070204832 F-2 R076477-SCA-3001 158 0159 GW eCTD TOC dment na Binefing Package for 4/1807 Type B Pre-NDA Meeting R076477-SCA-3001 162 0169 GW eCTD TOC dment na Binefing Package for 4/1807 Type B Pre-NDA Meeting R076477-SCA-3001 162 0169 GW eCTD TOC spondence na Bequest for a Type B CMC/Biopharmaceutics Pre-NDA R076477-SCA-	spondence	na		na	na	6429676	EDMS-PSDB-6429676	Ŋa
na Fax. US.JNJFOC.20070204832 Initial R076477-SCA.3001 155 6446121 EDMS-PSDB-6452312 na Letter: NB Waiver Granted for 126/07 SN 148 Submission R092670-PSY-3007 na 65526103 EDMS-PSDB-6452312 na Letter: NB Waiver Granted for 121/07 SN 148 Submission R092670-PSY-3007 156 0156 GW eCTD TOC na US-JNJFOC.20070203055 F-1 R076477-BIM-3004 156 0157 GW eCTD TOC different na US-JNJFOC.20070204832 F-1 R076477-BIM-3004 158 0158 GW eCTD TOC different na US-JNJFOC.20070204832 F-1 R076477-SCA-3001 161 0160 GW eCTD TOC different na US-JNJFOC.20070204832 F-2 R076477-SCA-3001 161 0160 GW eCTD TOC different na US-JNJFOC.20070204832 F-2 R076477-SCA-3001 161 0160 GW eCTD TOC spondence na US-JNJFOC.20070204832 F-2 R076477-SCA-3001 161 0162 GW eCTD TOC spondence na Change in Protocol and Statistical Analysis Plan <t< td=""><td>oort</td><td>na</td><td>US-JNJFOC-20070204832 Initial</td><td>R076477-SCA-3001</td><td>155</td><td>0155</td><td>GW eCTD TOC</td><td>na</td></t<>	oort	na	US-JNJFOC-20070204832 Initial	R076477-SCA-3001	155	0155	GW eCTD TOC	na
Description	oort	ηa	Fax: US-JNJFOC-20070204832 Initial	R076477-SCA-3001	155	6446121	EDMS-PSDB-6446121	na
The color of the	spondence	g	Letter: IRB Waiver Granted for 2/6/07 SN 150 Submission	R092670-PSY-3006	g	6452312	EDMS-PSDB-6452312	na
The Control of the	spondence	g g	Letter: IHB Waiver Granted for 1/31/07 SN 148 Submission	H0926/0-PSY-300/	Ja L	6526103	EDMS-PSDB-6526103	na
Idment na New Investigator R092670-PSY-3007 158 0158 GW eCTD TOC Idment na New Investigator Alex Investigator Alex Investigator Alex Investigator GW eCTD TOC GW eCTD TOC Int na US-JMJFOC-20070204832 F-2 R076477-SCA-3001 161 0160 GW eCTD TOC Idment na Change in Protocol and Statistical Analysis Plan. R092670-PSY-3002 162 0162 GW eCTD TOC spondence na Change in Protocol and Statistical Analysis Plan. R092670-PSY-3002 162 0163 GW eCTD TOC spondence na Change in Protocol and Statistical Analysis Plan. R092670-PSY-3002 165 GW eCTD TOC denert na Change in Protocol and Statistical Analysis Plan. R092670-PSY-3007 165 GW eCTD TOC denert na New and Updated Investigators R092670-PSY-3002 na 6614450 EDMS-PSDB-6614450 na lenal: SAP - Question about Submission Study R092670-PSY-3002 na 6637279 EDMS-PSDB-6637270 na Ema	ort	na Da	US-JNJFOC-20070204832 F-1	R076477-SCA-3001	157	0157	GW eCTD TOC	na
Independent New Investigator Processor FSY-3006 159 O159 GW eCTD TOC Int Briefing Package for 4/18/07 Type B Pre-NDA Meeting na 160 0160 GW eCTD TOC Int US-JNJFOC-220070204832 F-2 RQF677-SCA-3001 161 O161 GW eCTD TOC Intendment na Change in Protocol and Statistical Analysis Plan. RQ92670-PSY-3002 162 O162 GW eCTD TOC Spondence na Request for a Type B CMC/Biopharmaceutics Pre-NDA na 163 GW eCTD TOC Includent na Request for a Type B CMC/Biopharmaceutics Pre-NDA na 164 O164 GW eCTD TOC Includent na Clinical GW eCTD TOC GW eCTD TOC GW eCTD TOC Includence na Request for Submission Information RG92670-PSY-3007 na 661450 EDMS-PSDB-6614-50 Includence na Respondence na Respondence na GW eCTD TOC Includence na Email: Reply Information RGP eximention RGP eximention <td< td=""><td>nendment</td><td>na</td><td></td><td>R092670-PSY-3007</td><td>158</td><td>0158</td><td>GW eCTD TOC</td><td>na</td></td<>	nendment	na		R092670-PSY-3007	158	0158	GW eCTD TOC	na
na Briefing Package for 4/18/07 Type B Pre-NDA Meeting na 160 0160 GW eCTD TOC Indeed US-JNI/FOC-20070204832 F-2 R076477-SCA-3001 161 0161 GW eCTD TOC Idment na Change in Protocol and Statistical Analysis Plan R092670-PSY-3002 162 GW eCTD TOC spondence na Request for a Type B CMC/Biopharmaceutics Pre-NDA na 163 GW eCTD TOC spondence na Clinical GW eCTD TOC GW eCTD TOC dening na New and Updated Investigators R092670-PSY-3007 165 GW eCTD TOC denince na Email: SN 162 SAP - Question about Submission Study R092670-PSY-3002 na 6614450 EDMS-PSDB-6614450 pondence na Response to FDA RFI: Additional Salety Information na 661450 EDMS-PSDB-6637219 pondence na Email: SN 162 SAP Additional Salety Information na 6637270 EDMS-PSDB-6637279 na Email: SUGS SAP na na na 04-11-07 Email na	nendment	na		R092670-PSY-3006	159	0159	GW eCTD TOC	na
na US-JNJFOC-20070204832 F-2 R076477-SCA-3001 161 0161 GW eCTD TOC Idment na Change in Protocol and Statistical Analysis Plan. R092670-PSY-3002 162 0162 GW eCTD TOC spondence na Request for a Type B CMC/Biopharmaceutics Pre-NDA na 163 GW eCTD TOC nendment na Clinical GW eCTD TOC GW eCTD TOC deneting na New and Updated Investigators na 661450 GW eCTD TOC denetic na Email: Request for Submission Information na 661450 EDMS-PSDB-6614450 ndence na Email: SN 162 SAP - Question about Submission Study R092670-PSY-3002 na 6637219 EDMS-PSDB-6637219 ndence na Email: Reply to FDS's 4/507 Study Question R092670-PSY-3002 na 6637270 EDMS-PSDB-6637270 ndence na Email: SV162 SAP na na 04-11-07 Email na BO-JNJFOC-20060503643 F-1 R076477-BIM-3004 167 0167 GW eCTD TOC	dment	na	for 4/18/07	na	160	0160	GW eCTD TOC	na
Independence na Change in Protocol and Statistical Analysis Plan R092670-PSY-3002 162 0162 GW eCTD TOC spondence na Request for a Type B CMC/Biopharmaceutics Pre-NDA na 163 GW eCTD TOC nendment na Clinical GW eCTD TOC GW eCTD TOC deneting na New and Updated Investigators na 6614450 EDMS-PSDB-6614450 ndence na Email: SN 162 SAP - Question about Submission Study R092670-PSY-3002 na 6637219 EDMS-PSDB-6637219 spondence na Email: SN 162 SAP Additional Salety Information na 166 0166 GW eCTD TOC ndence na Email: Reply to FDS's 4/507 Study Question R092670-PSY-3002 na 6637270 EDMS-PSDB-6637270 ndence na Email: SV162 SAP na na 04-11-07 Email na RO-JNJFOC-20060503643 F-1 R092670-PSY-3001 167 0167 GW eCTD TOC na US-JNJFOC-20060503655 F-2 R076477-BIM-3004 168 0168 GW eCTD TOC	oort	Ľ,	US-JNJFOC-20070204832 F-2	R076477-SCA-3001	161	0161	GW eCTD TOC	กล
Spondence na Request for a Type B CMC/Biopharmaceutics Pre-NDA na 163 GW eCTD TOC nendment a Clinical na Clinical GW eCTD TOC GW eCTD TOC defined na Clinical GW eCTD TOC GW eCTD TOC GW eCTD TOC defined na Email: SN Log SAP - Question about Submission Study R092670-PSY-3007 na 661450 EDMS-PSDB-6637219 spondence na Email: SN Log SAP - Question about Submission Study R092670-PSY-3002 na 6637279 EDMS-PSDB-6637219 spondence na Email: Reply to FDS's 4/5/07 Study Question R092670-PSY-3002 na 6637270 EDMS-PSDB-6637270 ndence na Email: Reply to FDS's 4/5/07 Study Question R092670-PSY-3002 na 6637270 EDMS-PSDB-6637270 ndence na Email: SN 162 SAP na na 04-11-07 Email na ndence na RO-JNJFOCC-200660503643 F-1 R092670-PSY-3001 167 GW eCTD TOC na LOS SAP R0-11-07 Email R04-11-07 Email	mendment	2	Change in Protocol and Statistical Analysis Plan.	R092670-PSY-3002	162	0162	GW.eCTD.TOC.	na
lendment na Clinical GW eCTD TOC Idment na New and Updated Investigators R092670-PSY-3007 165 0165 GW eCTD TOC Indence na Email: Request for Submission Information na 6614450 EDMS-PSDB-6614450 Indence na Email: SN 162 SAP - Question about Submission Study R092670-PSY-3002 na 6637219 EDMS-PSDB-6637219 Spondence na Email: Reply to FDS's 4/5/07 Study Question R092670-PSY-3002 na 6637270 EDMS-PSDB-6637270 Indence na Email: S/162 SAP na 04-11-07 Email 04-11-07 Email Indence na RO-JNJFOC-20060503643 F-1 R092670-PSY-3001 167 GW eCTD TOC Indence na US-JNJFOC/20070203055 F-2 R076477-BIM-3004 167 GW eCTD TOC	orrespondence	na	Request for a Type B CMC/Biopharmaceutics Pre-NDA Meeting	na	163	0163	GW eCTD TOC	na
Indence na New and Updated Investigators R092670-PSY-3007 165 0165 GW eCTD TOC Indence na Email: Request for Submission Information na 6614450 EDMS-PSDB-6614450 Indence na Email: SN 162 SAP - Question about Submission Study R092670-PSY-3002 na 6637219 EDMS-PSDB-6637219 Spondence na Response to FDA RFI: Additional Safety Information R092670-PSY-3002 na 6637270 EDMS-PSDB-6637270 Indence na Email: S162 SAP na 04-11-07 Email na Indence na RO-JNJFOC-20060503643 F-1 R092670-PSY-3001 167 GW eCTD TOC na US-JNJFOC/20070203055 F-2 R076477-BIM-3004 168 GW eCTD TOC	Amendment	na	Clinical	na	28	0164	GW eCTD TOC	na
Indence na Email: Request for Submission Information na 6614450 EDMS-PSDB-6614450 Indence na Email: SN 162 SAP - Question about Submission Study R092670-PSY-3002 na 6637219 EDMS-PSDB-6637219 Spondence na Response to FDA RFI: Additional Safety Information R092670-PSY-3002 na 6637270 EDMS-PSDB-6637270 Indence na Email: S162 SAP na 04-11-07 Email Indence na RO-JNJFOC-20060503643 F-1 R092670-PSY-3001 167 GW eCTD TOC Indence na US-JNJFOC-20060503643 F-2 R076477-BIM-3004 167 GW eCTD TOC	mendment	na	New and Updated Investigators	R092670-PSY-3007	165	0165	GW eCTD TOC	na
Indence na Email: SN 162 SAP - Question about Submission Study R092670-PSY-3002 na 6637219 EDMS-PSDB-6637219 Epondence na Response to FDA RFI: Additional Safety Information R092670-PSY-3002 na 6637270 EDMS-PSDB-6637270 ndence na Email: S162 SAP na 04-11-07 Email ndence na RO-JNJFOC-20060503643 F-1 R092670-PSY-3001 167 GW eCTD TOC na US-JNJFOC/20070203055 F-2 R076477-BIM-3004 168 GW eCTD TOC	spondence	па	Email: Request for Submission Information	na	na	6614450	EDMS-PSDB-6614450	Па
Spondence na Response to FDA RFI: Additional Safety Information R092670-PSY-3002 na 6637270 EDMS-PSDB-6637270 ndence na Email: Reply to FDS's 4/5/07 Study Question na na na 04-11-07 Email: 04-11-07 Email ndence na RO-JNJFOC-20060503643 F-1 R092670-PSY-3001 167 GW eCTD TOC na US-JNJFOC/20070203055 F-2 R076477-BIM-3004 168 GW eCTD TOC	spondence	na	Email: SN 162 SAP - Question about Submission Study	R092670-PSY-3002	na	6637219	EDMS-PSDB-6637219	na
na Email: Reply to FDS's 4/5/07 Study Question R092670-PSY-3002 na 6637270 EDMS-PSDB-6637270 ndence na Email: S/162 SAP 04-11-07 Email 04-11-07 Email ndence na RO-JNJFOC-20060503643 F-1 R092670-PSY-3001 167 GW eCTD TOC na US-JNJFOC/20070203055 F-2 R076477-BIM-3004 168 GW eCTD TOC	prrespondence	na	Response to FDA RFI: Additional Safety Information	na	166	0166	GW eCTD TOC	na
ndence na na na 04-11-07 Email na RO-JNJFOC-20060503643 F-1 R092670-PSY-3001 167 GW eCTD TOC na US-JNJFOC/20070203055 F-2 R076477-BIM-3004 168 GW eCTD TOC	spondence	na		R092670-PSY-3002	na	6637270	EDMS-PSDB-6637270	na
na RO-JNJFOC-20060503643 F-1 R092670-PSY-3001 167 GW eCTD TOC na US-JNJFOC020070203055 F-2 R076477-BIM-3004 168 GW eCTD TOC	spondence	na	1	na	υa	na	04-11-07 Email	ηa
na US:JNUFOC020070203055 F-2 H076477-BIM-3004 168 0168 GW eCTD TOC	ort	na	RO-JNJFOC-20060503643 F-1	R092670-PSY-3001	167	0167	GW eCTD TOC	na
	ort	na	US-JNJFOC020070203055 F-2	R076477-BIM-3004	88	0168	GW eCTD TOC	ar

IND 67,356 (J	IND 67,356 (JNJ 16977831) (R092670) paliperidone palmitate	aliperidone p	palmitate			:	DP 227	
die D	Submission Tube	Date of Contact	Description	Protocol #	SN#	EDMS or Sequence #	Hyperlink	Garéway Receipt
2	FDA Correspondence	na	Email: Meeting Granted & Request for Meeting Pkg. By 5/10/07 S/163	กล		6733756	EDMS-PSDB-6733756	na
4/25/2007	Safety Report	na	DE-JNJFOC-20061200532 F-1	R076477-BIM-3004	170	0170	GW eCTD TOC	na
1	Safety Report	g	US-JNJFOC-20070405377 7-Day Initial	R076477-BIM-3004	171	0171	GW eCTD TOC	na
I.	FDA Correspondence	na	Fax: SN 171	na	g	6793658	EDMS-PSDB-6793658	na
	FDA Correspondence	na		Пã	g	6793660	EDMS-PSDB-6/93550	BE S
	FDA Correspondence	na		na	e (6801969	EUMS-PSUB-6801969	
5/4/2007	Safety Report	na	US-JNJFOC-20070405377 7-Day F-1	H076477-BIM-3004	7/1	2/10	GW BC1D 10C	2 6
	Safety Report	na	US-JNJFOC-20070404476 Initial	H076477-BIM-3001	2	01/3	GW ECID IOC	2
Γ	Safety Report	na	US-JNJFOC-20070405377 7-Day F-2	R076477-BIM-3004	174	0174	GW eC/U IOC	na
5/8/2007	Safety Report	na	US-JNJFOC-20070404476 F-1	R076477-BIM-3001	175	01/5	GW eCTD TOC	Tig
5/7/2007	FDA Correspondence	na	Meeting Minutes S/153	na	g (6806260	ELIMS-PSUB-b806250	Da C
5/9/2007	General Correspondence	na	Briefing Package for 6/7/07 CMC/Biopharmaceutics Type B pre-NDA Meeling	Па	176	0176	GW eCID IOC	liga
5/9/2007	Safety Report	па	US-JNJFOC-20070204832 F-3	R076477-SCA-3001	111	0177	GW eCTD TOC	na
5/9/2007	FDA Correspondence	na	Letter: 1/4/07 SN 145 Statistical Review with Comments	R092670-PSY-3007	E i	na	05-09-07 Letter	na
5/11/2007	General Correspondence	na		na	200	01/8	GW BCTD TOC	na
5/16/2007	Safety Report	na	US-JNJFOC020070201813 F-1	R076477-SCA-3002	179	0179	GW eC1D 10C	na
5/22/2007	Safety Report	na	US-JNJFOC-20070204832 F-4	R076477-SCA-3001	8	0180	GW eCID IOC	na
5/24/2007	Protocol Amendment	na	Change in Protocol; New Investigators	R092670-PSY-3006	181	0181	GW eCID IOC	na
5/25/2007	Information Amendment	กล	Nonclinical Pharmacology Study Report	na	182	0182	GW eCID IOC	na
6/4/2007	FDA Correspondence	na	Email/Attachment: Preliminary Comments for 6/7/07 Meeting		rg B	na	06-04-07 Email	na
6/8/2007	Record of Contact	6/8/2007	Protocol PSY-3001 "Fater" Qualifications	R092670-PSY-3001	eu ș	6963412	EUMS-PSUB-6963412	na
6/8/2007	Protocol Amendment	па	Change in Protocol; New Investigators	R092670-PSY-3007	2013	0183	GW eC ID TOC	na
6/14/2007	Protocol Amendment	na	New Protocol	H092670-PSY-1008	Ž į	5 6	COT CITO WE	Ta C
6/15/2007	General Correspondence	na	IRB Waiver Request	H0926/0-PSY-1008	282	0183	06-15-07 Fmail	29 29
6/15/2007	FDA Correspondence	g ;	FINAL OCIONA OFFICIAL MOSTICS MISSINGS		2 2	e.	06-29-07 Letter	na
6/29/2007	FDA Correspondence	g g	Charge is Deviced Meeting Minutes	.1	186	0186	GW esig Toc	ag .
//31/200/	Protocol Amendment	2 2	Now Invotigators	B092670-PSY-3007	187	0187	GW eSIG TOC	na
8/1/2007	Protocol Amendment	ā	Clarifogue of Official Misures of the O7 Ture 2007 Meeting	000000000000000000000000000000000000000	<u> </u>	0188	GW ASIG TOC	na
8/13/2007	General Correspondence	<u>e</u>	Clarification of Official Militates of the Official Michigan CMC & Biopharmaceutics pre-NDA	5 11	3	3		
8/21/2007	Safety Report	па	DE-JNJFOC-20061200532 F-2	R076477-BIM-3004	189 89	0189	GW eSIG TOC	na
8/27/2007	General Correspondence	na	Sample Dataset Submission for IT Testing	na	98	0190	GW esig TOC	g
9/12/2007	FDA Correspondence	na	Email: Paliperidone palmitate NDA Submission Plans	na	g	g	09-12-07 Email	Ba
9/19/2007	Protocol Amendment	В	Change in Protocol; New Investigators	R092670-PSY-1008	191	1910	GW ESIG TOC	E S
9/20/2007	Annual Report	ВП	Reporting Period: 07/20/06 - 07/19/07	na	192	0192	GW esig 100	E 3
11/1/2007	Protocol Amendment	na	New Investigators	H092670-PSY-3007	33	0193	SW BSIG IOC	I.a
11/2/2007	Protocol Amendment	na		H0926/U-PSY-3006	5 5	40.00	GW ESIG TOC	118
11/29/2007	Safety Report	ηġ	DE-JNJFOC-20061200532	HU/04//-BIM-3004	CS.	0180	20 Disa WD	212
12/6/2007	Record of Contact	6/16/2004	Minutes of June 16,2004 CMC/Biopharmaceutics End of Phase 2 Meeting for Palineridon Palmitate	na	e.	na	12-06-07 Email	na
12/11/2007	Information Amendment	ec	CMC Drug Substance, Drug Product and Stability Data	na	196	0196	GW eSIG TOC	na
12/21/2007	General Correspondence	na	Request for Proposed Proprietary Name Review	na	197	0197	GW eSIG TOC	Па
12/27/2007	Protocol Amendment	ηg	New Investigators	R092670-PSY-3006	198	0198	GW eSIG TOC	га
1/9/2008	Information Amendment	ηa	Pharmacology/Toxicology	na	199	0199	GW eSIG TOC	Ľ.
1/15/2008	Protocol Amendment	ъ	1	R092670-PSY-3007	500	0200	GW eSIG TOC	na
1/23/2008	Protocol Amendment	na	Statistical Analysis Plan for R092670-PSY-3007	R092670-PSY-3007	201	0201	GW eSIG TOC	na
1/25/2008	General Correspondence	па	Postmarketing Study Commitment Final Report: Developmental Toxicity Study in the Rat Final Report	В	502	0202	GW eSIG TOC	na
1/30/2008	FDA Correspondence	ā	Email/Attachment: IRB Waiver Granted	na	na	na	01-30-08 Email	, na
2/1/2008	Protocol Amendment	na	New Investigators	R092670-PSY-1008	203	0203	GW eSIG TOC	па

Gateway Receipt	na	na	па	na	na	na	na	กล	na	na	na	na	na	na	D11	RI :	na	na	na	na	na	na	na		67356-0220_eSIG	67356-0221 eSIG	67356-0222 eSIG	6/35b-0222 eSig								
Hvoerlink	02-08-08 Fax	GW eSIG TOC	GW eSIG TOC	GW eSIG TOC	GW eSIG TOC	GW eSIG TOC	04-09-08 Email	GW eSIG TOC	GW eSIG TOC	04-28-08 Email	07-14-08 Email	GW eSIG TOC	GW eSIG TOC	GW esig TOC	ON ESIG TOO	GW esign 100		GW eSIG TOC	GW eSIG TOC	GW eSIG TOC	GW eSIG TOC	09-30-08 Email	10-16-08 Email	GW eSIG TOC	GW eSIG TOC	GW eSIG TOC	GW eSIG TOC	GW esig 100								
EDMS of Septions	na	0204	0205	90206	0207	0208	na	0209	0209	na	na	0210	0211	0212	0213	0214		0215	0216	0217	0218	na	na	0219	0220	0221	0222	0222								
# V	,,	204	205	206	207	208	na	209	209	na	na	210	211	212	213	214		215	216	217	218	na	na	518	220	221	222	222								
Protocol		R092670-PSY-3007	R092670-PSY-3006	R092670-PSY-3007	R092670-PSY-3006	R076477-SCA-3001	R092670-PSY-3007	R092670-PSY-1008	na	R092670-PSY-3007	na	R076477-PSZ-3001	па	R076477-PSZ-3001	H0/64//-P52-3001	na		R092670-PSY-1008	na	R076477-SCA-3002	na	na	na	na	R076477-BIM-3004	na	R092670-SCH-3004	na								
Longitudes C.	Eav. SN 0004	B. 10. IE. C. 2007070701878 Initial	New Investigators	New Investigators	Change in Protocol; New Investigators	US-JNJFOC-20070204832	Email: SN 201 Study R092670-PSY-3007 Statistical Analysis Plan	Change in Protocol	CMC	Fmail/Attachment: Statistical Analysis Plan	Email/Attachments: Study Question	US-JNJFOC-20080704122 Initial	Type B End-of-Phase 2/Pre-Phase 3 Meeting Request	IN-JNJFOC-20080704122 F-1	IN-JNJFOC-20080704122 F-1	Briefing Package for 7 Oct 2008 Type B End-of-Phase 2/Pre-	available electronically.	Change in Protocol	Benorting Period: 07/20/07 - 07/19/08	IN-JNJFOC-20070201813 F-2	Updated Clinical Protocol Summary for 07Oct2008 Type C	Preliminary Comments for Oct 7 Meeting	Email/Attachments: Paliperidone palmitate Meeting Minutes	Minutes of the 70ct08 End of Phase 2/Pre-Phase 3 Mtg.	DE-JNJFOC-20061200532 F-4	Updated Investigator's Brochure, Edition 9, 02/25/08	New Protocol	Justification for Suicidality Assessment								
Date of		T	2 2		na	na	Б	na	Γ	Π	na	na	па	na	na	na	c are only	מונה ביוווץ	2 2	60	na	na	Ba	2	g	na	na	БП								
	Submission: ype	\top	2/8/2008 Safety Report	1	Т	1	1	4/21/2008 Protocol Amendment	Т	+	1	Т	Т	1	8/25/2008 Safety Report		This course of the second SACs are only available electronically.	Over Energy Garage Amendment	_	T	7	6/30/2008 EDA Correspondence	_		_	Т	L	Г	П							

Gateway Receipt ā 5 B ā 2 ā g 멸 ā කි කි na 뗠 ē <u>ක</u> කි g na a g Ē 띰 Da ē 힐 g 2 2 Ē ā g Ē ā 8 B na **8** 8 g EDMS-PSDB-3907677 EDMS-PSDB-3909784 EDMS-PSDB-3928113 EDMS-PSDB-3548304 EDMS-PSDB-3474299 EDMS-PSDB-3479851 EDMS-PSDB-3514273 EDMS-PSDB-3681428 EDMS-PSDB-3699361 EDMS-PSDB-3704542 EDMS-PSDB-3723435 EDMS-PSDB-3728621 EDMS-PSDB-2931978 EDMS-PSDB-2937288 EDMS-PSDB-3044512 EDMS-PSDB-3195694 EDMS-PSDB-3288697 EDMS-PSDB-3397560 EDMS-PSDB-3442328 EDMS-PSDB-3868773 EDMS-PSDB-3902895 EDMS-PSDB-3732055 EDMS-PSDB-3776556 EDMS-PSDB-3756672 EDMS-PSDB-3810109 EDMS-PSDB-3860095 EDMS-PSDB-3928067 EDMS-PSDB-3862824 Original IND EDMS-PSDB-2651976 EDMS-PSDB-2676686 EDMS-PSDB-2683477 EDMS-PSDB-3594054 EDMS-PSDB-3599384 EDMS-PSDB-3818660 EDMS-PSDB-2656702 EDMS-PSDB-3609437 EDMS-PSDB-3230681 3902895 3907677 3909784 3928113 3756672 3810109 3818660 3928067 3862824 3548304 3681428 3699361 3704542 3723435 2697285 2716903 3479851 3514273 3594054 3776556 3868773 2676686 2931978 2937288 3044512 3195694 3230681 3288697 3397560 3732055 3860095 3599384 2656702 2651976 2683477 372862 Sequence # **EDMS of** 010 019 020 020 021 028 028 a 012 013 014 52 SS 85 a a 8 026 015 024 100 an ë na ā R076477-PSY-3004 R092670-SCH-201 R092670-SCH-201 R092670-SCH-201 na R092670-SCH-704 R092670-SCH-201 R076477-SCH-303 R092670-SCH-201 R076477-SCH-304 na R076477-SCH-304 R076477-SCH-303 R092670-SCH-201 na R092670-USA-3 5 ä 뗩 ם ā g 8 B g 8 5 8 8 g ā g **8** 8 2 쯀 8 Request for List of Nonclinical Studies Submitted Under IND Minutes of 6/16/04 CMC/Biopharmaceutics End of Phase 2 Briefing Package for 9/28/04 End of Phase 2 Meeting Request for Special Protocol Assessment: Carcnogenicity Minutes of the 9/28/04 End of Phase 2 Meeting and Post-Notice of Intent to Request Special Protocol Assessment: Fax: Response to Carcinogenicity Protocol Assessment Request - Final CAC Report Request for Type B End of Phase 2 Meeting - Chemistry, Request for Additional Desk Copies and IND Number for Response to FDA Request in 10/12/04 End of Phase 2 Follow-up Information for Request for Special Protocol Briefing Package for 6/16/04 CMC/Biopharm Meeting Minutes of the 9/28/04 End of Phase 2 FDA Meeting Minutes of 6/16/04 Type B End of Phase 2 Meeting Clearance to Proceed with the Studies Under IND Fax: Notice of Intent to Request Special Protocol Assessment: Carcinogenicity SN 021 Request for a Type B End-of-Phase 2 Meeting Microbiology, and Biopharmaceutics Letter: Meeting Request Granted for 6/16/04 Response to Request from Dr. Lois Freed Response to Request by Review Chemist Response to Request by Review Chemist Assessment: Carcinogenicity Protoco etter: IND Acknowledgement Letter Fax: 10/26/04 Submission SN 024 Meeting for Paliperidone palmitate Request for a Type C Meeting US-JNJFOC-20041100394 Initial Reporting Period: 6/7/03 - 6/6/04 IN-JNJFOC-20040800656 Initial CMC/Biopharm Meeting Minutes New Protocol; New Investigator New Investigators US-JNJFOC-20040304794 Initial CMC; Pharmacology/Toxicology New Protocol; New Investigator US-JNJFOC-20040304794 F-1 Meeting Follow-up Information IN-JNJFOC-20040800656 F-1 Original IND (50 Volumes CMC/Biopharmceutics Paliperidone palmitate New Investigators New Investigators New Investigators New Investigators New Investigators Carcinogenicin Protocol 9/28/2004 6/16/2004 5/13/2003 5/19/2003 na na 6/2/200 8 8 8 **8** 8 5 5 5 5 g Га 면 명 명 8 8 8 ē 8 8 8 8 띰 8 8 8 8 8 8 8 g ā Conta General Correspondence General Correspondence General Correspondence FDA Correspondence General Correspondence General Correspondence General Correspondence Safety Report General Correspondence General Correspondence General Correspondence General Correspondence General Correspondence Information Amendmen FDA Correspondence FDA Correspondence FDA Correspondence Record of Contact FDA Correspondence Protocol Amendment Protocol Amendment Protocol Amendment Protocol Amendment Protocol Amendmen Protocol Amendment Protocol Amendment Protocol Amendment Record of Contact Record of Contact Record of Contact Record of Contact IND Amendment IND Amendment IND Amendment Safety Report Safety Report Annual Report Safety Report Safety Report Original IND 10/26/2004 11/10/2004 9/12/2003 9/9/2004 10/26/2004 0/28/2004 11/15/2004 8/25/2004 0/26/2004 6/2/2003 6/5/2003 9/11/2003 2/11/2004 3/31/2004 5/6/2004 5/10/2004 8/12/2004 11/9/2004 8/27/2004 4/29/2004 5/20/2004 6/16/2004 6/28/2004 7/1/2004 8/4/2004 8/17/2004 5/6/2003 1/9/2004 /23/2004 5/19/2003 5/30/2003 9/2/2004

	Date of		Brower #	a No	FUMS of Sequence #	Hyberlink	design (public)
Submission Type	Contact	CMC		0	3928878	EDMS-PSDB-3928878	na
-	2 2	1.15. IN IEOC. 20041102371 Initial	R076477-SCH-304	031	3931421	EDMS-PSDB-3931421	na
_	2 0	- 😽	R076477-SCH-304	032	3938295	EDMS-PSDB-3938295	na
_	2 2	-	R076477-SCH-304	na	3961743	EDMS-PSDB-3961743	пa
11/23/2004 FDA Correspondence	2 60	I.I.S.: IN.IFOC-20041102371 F-1	R076477-SCH-304	033	3949874	EDMS-PSDB-3949874	na
\top	l eu	Pharmacology/Toxicology; Clinical	na	034	3955196	EDMS-PSDB-3955196	na
-	na	US-JNJFOC-20041103584 F-1	R076477-SCH-304	035	3961376	EDMS-PSDB-3961376	na S
Т	Па	MY-JNJFOC-20041105754 Initial	R076477-SCH-705	936	3963269	EDMS-PSDB-3963269	na
7	na	Pharmacology/Toxicology	na	037	3967273	EDMS-PSDB-396/2/3	na
Τ.,	na	US-JNJFOC-20041201617 Initial	R076477-SCH-701	038	3976131	EDMS-PSDB-39/6131	E C
_	na	IN-JNJFOC-20041202092 Initial	R076477-SCH-703	650	3998127	EDMS-PSDB-3998127	na Se
-	па	Briefing Package for 1/13/05 Meeting	na	040	3998804	EDMS-PSUB-3938804	III
7	па	CA-JNJFOC-20041204345 Initial	R076477-SCH-305	8	4008929	EUMS-PSUB-4008929	PI
_	æ	MY-JNJFOC-20041105754 F-1	R076477-SCH-705	042	4007899	EDMS-PSUB-4007888	18
_	na	MY-JNJFOC-20041204460 Initial	R076477-SCH-705	283	4010952	FUMS-FSDB-4010932	000
$\overline{}$. na	IN-JNJFOC-20041202092 F-1	H076477-SCH-703	044	4010959	EDM3-F3D3-40 (9939	800
_	na	MY-JNJFOC-20041105754 F-2	H076477-SCH-705	243	4010900	EDM3-1-30-4010363	2 6
-	na	CA-NJFOC-20041204345 F-1	R076477-SCH-305	049	4019807	CONS-1 305-1 3001	5
Т	na	New Protocol; New Investigator	R092670-PSY-3001	ž s	4023920	EDMS-PSDB-4023320	000
	na	MY-JNJFOC-20041105754 F-3	R076477-SCH-705	8	404504	EDMS-F308-4020237	200
1/14/2005 Safety Report	na	US-JNJFOC-20041100394 F-1	HU/64//-SCH-/04	200	4042311	EDMS PSDB-405051	2 60
_	na	Pharmacology/Toxicology	י חשר יויים דרי אראם	020	402022	EDIMS-F SUB-4050321	5 20
•	กล	PL-JNJFOC-20041206244 Initial	H076477-5CH-703	ich	4050379	CDMS-0500-40503/3	800
1/19/2005 Safety Report	na	US-JNJFOC-20050103392 Initial	H0/64//-SCH-/01	ZCO	4030130	EDMS DSDB-4063491	80
1/19/2005 FDA Correspondence	na	Fax: Safety Report SN 052	HU/64//-SCH-/UI	2 5	4000491	EDIMS: DEDB.4063105	80
1/21/2005 Safety Report	па	US-JNJFOC-20050103392 F-1	HU/64//-SCH-/UI	200	4003193	EDAMS DSDR-4086354	2 60
	าล	CA-JNJFOC-20041204345 F-2	H0/64//-3CH-303	250	4000034	EDMS-PSDB-4070650	60
1/26/2005 Safety Report	na	US-JNJFOC-20050103392 F-2	HO76477-3001-301	000	4002677	FDMS-PSDB-409677	60
	па	US-JNJFOC-20050105338 Initial	HU/04//300-1000	257	4032077	EDMS-PSDB-4093088	Da
	па	New Investigators	F02577-501-5004	058	4094614	EDMS-PSDB-4094614	na na
7	na	IN-UNDFUC-2004 IZUZUSZ F-Z	B076477-SCH-704	059	4098820	EDMS-PSDB-4098820	na
_	na Pa	US-JNUF-UC-ZUD4 (100384 F-Z	R076477-SCH-305	090	4098827	EDMS-PSDB-4098827	na
_	<u> </u>	MIT-JINGFOU-ZUOSU 10340Z HIRISH	R076477-SCH-301	061	4115429	EDMS-PSDB-4115429	เกล
\neg	2 6	FOX. Sofati Booot SN 061	R076477-SCH-301	g	4140901	EDMS-PSDB-4140901	na
	<u> </u>	11S-1N FOC-20050105338 F-1	R076477-SCH-305	790	4119644	EDMS-PSDB-4119644	na
2/14/2003 Salety hebbit	e	MY-JNJF)C-20050105402 F-1	R076477-SCH-305	903	4128519	EDMS-PSDB-4128519	na
1	na	RO-JNJFOC-20050201375 F-1	R076477-SCH-301	8	4137747	EDMS-PSD8-413//4/	ga
1	na	US-JNJFOC-20050304957 Initial	R076477-SCH-1009	965	4209442	EDMS-PSUB-4209442	23
\top	na	Fax: Safety Report SN 065	R076477-SCH-1009	na	4210799	EDMS-PSDB-4210/99	na
1	na	US-JNJFOC-20050304957 F-1	R076477-SCH-1009	990	4224908	EUMS-PSUB-4224908	ua 2
Т	na	TW-JNJFOC-20050305349 Initial	R076477-SCH-305	/90	4233955	FDMS-FSUB-4233933	19
Τ	υg	MY-JNJFOC-20041204460 F-1	R076477-SCH-705	888	4255811	FUMS-PSUB-4255811	Z C
-	na	MY-JNJFOC-20041204460 F-2	R076477-SCH-705	690	4259582	FUMS-FSUB-4239362	a
T-	Па	NL-JNJFOC-20050402753 Initial	PALIOROS-SCH-1011	9/0	4267510	FUMS-PSUB-426/310	II a
1-	na	Fax: Safety Report SN 070	PALIOHOS-SCH-1011	na Sz.	42/8984	FUMS: F3DB-4270304	200
т	na	US-JNJFOC-20050105338 F-2	H076477-SCH-305	1/0	42/9/4/	THAT DOUBLE 19747	200
Т	пa	MY-JNJFOC-20041105754 F-4	R076477-SCH-705	072	42/9/61	EDWS-PSUB-42/9/01	110
1	na	US-JNJFOC-20041100394 F-3	R076477-SCH-704	073	4279122	EDMS-F300-42/3122	218
┿	na	NL-JNJFOC-20050402753 F-1	PALIOHOS-SCH-1011	0/4	4287661	EDMS-F305-4201001	200
Г	na	Reclassification of IND Safety Reports	na crossed	6/0	4322913	EDMS-PSDB-4320789	5 60
5/9/2005 Protocol Amendment	па	New Protocol; New Investigator	HU926/U-P31-3003	0/0	4322103	בטוויסבן סמקי בספרי אין	2

•

Gateway Recelpt g 2 2 na g g na ā 8 필밀 Ē g g ā ß නි කි 宫 g na Ë g g ଜ 쮿 a 8 8 8 ä a ē E E E na 열 열 g 2 пa 2 2 2 EDMS-PSDB-5029714 EDMS-PSDB-5030729 EDMS-PSDB-5040289 EDMS-PSDB-5131076 EDMS-PSDB-5205422 EDMS-PSDB-4520333 EDMS-PSDB-4525548 EDMS-PSDB-4529100 EDMS-PSDB-4574605 EDMS-PSDB-4586146 EDMS-PSDB-4692158 EDMS-PSDB-4925304 EDMS-PSDB-4951293 EDMS-PSDB-4966845 EDMS-PSDB-4424386 EDMS-PSDB-4431011 EDMS-PSDB-4441911 EDMS-PSDB-4460769 EDMS-PSDB-446586 EDMS-PSDB-4343153 EDMS-PSDB-4348879 EDMS-PSDB-4354981 EDMS-PSDB-4362170 EDMS-PSDB-4381574 EDMS-PSDB-1103047 EDMS-PSDB-4411736 EDMS-PSDB-4411745 EDMS-PSDB-4416120 EDMS-PSDB-5019672 EDMS-PSDB-4758438 EDMS-PSDB-4762944 EDMS-PSDB-4764829 EDMS-PSDB-4531527 EDMS-PSDB-4544136 EDMS-PSDB-4565568 EDMS-PSDB-4821292 EDMS-PSDB-4771325 EDMS-PSDB-4867147 EDMS-PSDB-4477198 EDMS-PSDB-4484198 EDMS-PSDB-4411495 EDMS-PSDB-4414564 EDMS-PSDB-4421865 EDMS-PSDB-4325611 EDMS-PSDB-4329282 5030729 5040289 5131076 4758438 4821292 4762944 4764829 4771325 4867147 4925304 4951293 5029714 5205422 4520333 4525548 4529100 4586146 4692158 4348879 4354981 4362170 4411745 4416120 4414564 4460769 4465586 4477198 4544136 4565568 4574605 4966845 5019672 4329282 4343153 4424386 4431011 EDMS or Sequence # 4482015 4484198 4421835 4381574 4403047 4411495 4441911 113 116 106 5 5 5 112 117 \$ 55 E 108 5 5 5 5 E ä 085 086 8888 092 079 ##.ss R092670-PSY-3004 R076477-SCH-301 R076477-SCH-705 R076477-SCH-705 R076477-SCH-705 R076477-SCH-705 R092670-PSY-3002 R092670-PSY-3004 R092670-PSY-1001 PALIOROS-P01-1011 R076477-SCH-301 R092670-PSY-1004 R092670-PSY-1004 R092670-PSY-1004 R076477-SCH-1009 R092670-PSY-3001 R076477-SCH-1009 R076477-SCH-1009 R076477-SCH-705 R076477-SCH-705 -3004 na R092670-PSY-1004 na R092670-PSY-1002 na R076477-SCH-705 na R092670-PSY-1002 R092670-PSY-3001 R092670-PSY-3004 R092670-PSY-3005 R092670-PSY-3003 R076477-SCH-301 R076477-SCH-705 R076477-SCH-705 R076477-SCH-301 R076477-SCH-301 R092670-PSY ğ g 2 na В g FDA Acceptance of Amended Drug Production Registration Report Received from Sterling IRB Regarding CBH Health Request for Review of Revised Drug Product Registration New Protocol: New Investigators Request for Review of Revised Drug Product Registration Request for Review of Drug Product Registration Stability Minutes of the 12/7/05 Bipolar I Disorder End-of-Phase Minutes of the 12/7/05 End of Phase 2 Meeting CA-JNJFOC-20051101512 F-2 CA-JNJFOC-20051101512 F-3 New Protocol: New Investigators 1. Martynowicz is Now Primary Contact Reporting Period: 06/07/04 - 06/06/05 New Protocol; New Investigators Fax: Report to FDA from Sterling IRB Description RO-JNJFOC20050201375 F-2 CA-JNJFOC-20051101512 Initial CA-JNJFOC-20051101512 F-1 Initial New Protocol; New Investigators New Protocol; New Investigators US-JNJFOC-20050603607 Initia New Protocol; New Investigators MY-JNJFOC-20041204460 F-3 IN-JNJFOC-20050503897 Initial Investigator's Brochure: Agenda MY-JNJFOC-20041204460 F-5 MY-JNJFOC-20041204460 F-4 NL-JNJFOC-20050402753 F-2 US-JNJFOC-20041201617 F-1 US-JNJFOC-20050103392 F-3 US-JNJFOC-20050304957 F-2 US-JNJFOC-20050603607 F-1 JS-JNJFOC-20050502821 Fax: Safety Report SN 079 IN-JNJFOC-20050503897 IN-JNJFOC-20050503897 Stability Protocol for F013 2/Pre-Phase 3 Meeting Change in Protocol New Investigators New Investigators New Investigators Change in Protocol Stability Protocol **New Investigators** Stability Protocol New Invest Protocol CM&C CM&C 9/26/2005 2/7/2005 8 8 8 8 8 g g g 8 8 8 8 8 8 8 g 8 8 8 8 Date of Contact a a a g <u>කි</u> කි 2 2 2 g 멸멸멸 па 5 5 5 5 E na **国 国 国** na General Correspondence Safety Report General Correspondence General Correspondence Information Amendment Information Amendment Information Amendment Information Amendment Information Amendment Information Amendment 12/29/2005 Safety Report 2/2/2006 Protocol Amendment 2/23/2006 Protocol Amendment FDA Correspondence Protocol Amendment Submission Type Safety Report FDA Correspondence Protocol Amendment Protocol Amendment Protocol Amendment Protocol Amendmeni Protocol Amendmeni Protocol Amendment Protocol Amendment Record of Contact Record of Contact Record of Contact ND Amendment IND Amendment IND Amendment Safety Report Safety Report Annual Report Safety Report Salety Report Safety Report 9/29/2005 9/30/2005 9/30/2005 10/26/2005 12/22/2005 12/29/2005 2/2/2006 11/11/2005 11/21/2005 11/29/2005 2/21/2005 6/29/2005 7/1/2005 7/6/2005 12/20/2005 6/15/2005 6/15/2005 6/15/2005 6/17/2005 7/19/2005 7/20/2005 7/21/2005 9/26/2005 8/5/2005 8/5/2005 9/9/2005 6/16/2005 7/15/2005 5/10/2005 5/11/2005 5/16/2005 5/16/2005 5/25/2005 5/25/2005 6/10/2005 6/28/2005 9/27/2005 5/23/2005 6/13/2005 6/14/2005 8/1/2005 6/14/2005 7/6/2005

Gareway Receipt	60	80	na	na	na	na	na	Па	na	na	na		Гла	na	60	E C	na	na	na	na	na	na	na	80 00	Da U	na Pa	ВП	E E	na	na	na na	E S	20 00	E L		ηa	ηa	na	пa	na	na	na	na	na	na	na
Hyperfink	EDMS-PSDB-5248420	EDMS-PSDB-5324478	EDMS-PSDB-5358805	EDMS-PSDB-5330146	EDMS-PSDB-5352966	EDMS-PSDB-5546925	EDMS-PSDB-5545009	EDMS-PSDB-5593354	EDMS-PSDB-5617192	EDMS-PSDB-6380254	EDMS-PSDB-5645851		EDMS-PSDB-5662755	EDMS-PSDB-5704533	EDMC. PSDB. 5714981	EDMS-PSDB-6033820	EDMS-PSDB-5755623	EDMS-PSDB-5765064	EDMS-PSD8-5799979	EDMS-PSDB-5827016	EDMS-PSDB-5838723	EDMS-PSDB-5922314	EDMS-FSDB-366640	EDMS-PSD8-5895887	EDMS-PSDB-5922505	EDMS-PSDB-5922449	EDMS-PSDB-5922559	EDMS-PSDB-5922643	EDMS-PSDB-5922614	EDMS-PSDB-5908836	GW eCID IOC	GW eCID TOC	EDMS-PSDR-6027759	EDMS-PSDB-6058010		GW eCTD TOC	GW eCTD TOC	GW eCTD TOC	EDMS-PSDB-6159463	EDMS-PSDB-6163931	GW eCTD TOC	GW eCTD TOC	GW eCTD TOC	GW eCTD TOC	EDMS-PSDB-6218032	GW eCTD TOC
EDMS or Sequence #	5248420	5324478	5358805	5330146	5352966	5546925	5545009	5593354	5617192	6380254	5645851		5662755	5704533	57148R3	6033820	5755623	5765064	5799979	5827016	5838723	5922314	5000040	5895887	5922505	5922449	5922559	5922643	5922614	5908836	0000	0134	6027759	6058010		0136	0137	0138	6159463	6163931	0139	0140	0141	0142	6218032	0143
#NS	<u>_</u>	119	119	120	121	na	na	122	123	na	124		125	Пâ	82	БГ	126	127	gu	128	129	a S	3 8	131	na	ηa	na	na	g	35.	3 5	13. E	g	na		136	137	138	g	na	139	140	141	142	па	143
Protocol#	na	R076477-SCH-701	R076477-SCH-701	R092670-PSY-3004	R076477-SCH-701	R092670-PSY-3004	R092670-PSY-3004	R092670-PSY-3003	R092670-PSY-3003	na	R092670-PSY-3001;	R092670-PSY-1004	R076477-SCH-701	R092670-PSY-3001; R092670-PSY-3002; R092670-PSY-3004	R092670-PSY-3003	na	กล	na	na	na Dono 477 Dia 6000	HU/64//-BIM-3002	na	80	R076477-SCA-3003	па	na	na	na	na	HU/64 / 7-61M-3002	D076477 CCU 704	R076477-RIM-3002	na	na		R092670-PSY-3001	na	R076477-BIM-3002	na	R092670-PSY-3001	R092670-PSY-3002	Multiple	R076477-BIM-3004	R092670-PSY-3001	na	R092670-PSY-3005
Description	IRB Waiver Request	IN-JNJFOC-20060205306 7/15 Day Initial	Fax: IN-JNJFOC-20060205306 7/15 Day Initial	Clinical: Statistical Analysis Plan for R096270-PSY-3004	Fax: IN-JNJFOC-20060205306 7/15 Day F-1	Letter: IRB Waiver Request Granted (S-117)	Email/Attachment: IRB Wavier Request Granted (S-117)	Protocol R092670-PSY-3003 Medication Kit Error	-	-	Clinical		IN-JNJFOC-20060205306 F-2	Email/Attachment: Poland Investigator Site Audit with CL for SN 124	Email: SAP for R092670-PSY-3003	Email: FDA Response to Statistical Questions from 6/26/06		Gen Corr: Request for Type B Pre-Phase 3 Meeting	- 17	Iden Corr. Request for Type C Meeting	Emolifothaniati Madian Danial	Reporting Period: 06/07/05 - 06/06/06	Email: Electronic Submissions	Request for Special Protocol Assessment	Email: Meeting Granted	Email: Bipolar & Schizophrenia Meeting Requests	Email; Bipolar & Schizophrenia Meeting Requests		Email: Meeting Granted (3:22pm)	ACTD Submission Conversion	IN. IN IECC. PORRODS 2014 Day E.3	IN-JNJFOC-20060805629 F-2	Email: Transfer of Regulatory Responsibility	Letter: RFI in Response to 9/21/06 Request for Special	Protocol Assessment	Cinical, Statistical Analysis Plan for PSY-3001	Briefing Pkg. For 12/11/06 Type C Meeting	IN-JNJFOC-20060805629 F-3	Email: N136 Stats Comments	Email/Attachment: N136 Stats Comments	SE-JNJFOC-20061005337	Multiple (9)	DE-JNJFOC-20061200532 I	na Clinical: Statistical Analysis Plan for R092670-PSY-3001	Minutes from the Meeting with the FDA Division of Psychiatry Products on 12/11/06	
Date of Contact	na	na	na	na	na	Па	na	Za Za	ηa	6/23/2006	na		ng B	na B	gu	na	Ba	na	E :	E S	010	g e	na	na	Па	na	g	E :	g	2	ec	па	na	เมล		Па	na	па	Па	na	na	na	na	na	12/11/2006	na
Submission Type	General Correspondence	Safety Report	General Correspondence	Information Amendment	General Correspondence	FDA Correspondence	FDA Correspondence	IND Amendment	Information Amendment	Record of Contact	Information Amendment		Safety Report	FDA Correspondence	FDA Correspondence	FDA Correspondence	IND Amendment	IND Amendment	FDA Correspondence	Safaty Report	EDA Correspondence	Annual Report	FDA Correspondence	General Correspondence	FDA Correspondence	FDA Correspondence	FDA Correspondence	FUA Correspondence	FUA Correspondence	General Correspondence	Safety Benort	Safety Report	FDA Correspondence	FDA Correspondence	Information Amondana	mornialion Americinent	General Correspondence	Salety Report	FUA Correspondence	FUA Correspondence	Salety Report	Safety Report	7	dment		12/22/2006 Protocol Amendment
Date	3/6/2006	3/24/2006	3/24/2006	3/27/2006	4/3/2006	5/26/2006	5/26/2006	6/20/2006	6/26/2006	6/27/2006	7/11/2006		7/12/2006	1//2006	7/21/2006	7/31/2006	8/10/2006	8/14/2006	8/1//2006	9/1/2006	9/12/2006	9/18/2006	9/20/2006	9/21/2006	9/22/2006	9/22/2006	9/25/2006	9/26/2006	9/26/2006	10/6/2006	10/11/2006	\mathbf{T}		11/3/2006	11/6/2006	11/0/2000		_	_	_	_	_	-	_	12/21/2006	12/22/2006

Gateway. Receipt

8 8 8 2 2 B 5 ā 밀밀 ā Б 5 5 E ā 멸멸 절 절 2 E g 宫 2 2 g 8 8 8 밀밀 g ā ā **B B** g ē 宫 ā ä 9 GW eCTD TOC GW eCTD TOC EDMS-PSDB-6416129 EDMS-PSDB-6415933 EDMS-PSDB-6452312 EDMS-PSDB-6526103 GW eCTD TOC GW eCTD TOC GW eCTD TOC EDMS-PSDB-6264901 EDMS-PSDB-6614450 EDMS-PSDB-6637219 EDMS-PSDB-6429676 GW eCTD TOC EDMS-PSDB-6446121 EDMS-PSDB-6308521 EDMS-PSDB-6360613 EDMS-PSDB-6324934 EDMS-PSDB-6248267 EDMS-PSDB-6241885 EDMS-PSDB-6383191 EDMS-PSDB-66372 GW eCTD TOC 04-11-07 Email GW eCTD TOC GW eCTD TOC GW eCTD TO GW eCTD GW eCTD GW eCT 6614450 6637219 0166 6415933 154 6429676 0155 6446121 6452312 6526103 0156 6416129 6637270 6248267 6241885 0146 6264901 6308521 6360613 6324934 0169 0163 0164 0165 0168 6383191 0157 0158 0159 па 0167 0160 0161 0162 0148 0149 0150 0152 0145 0151 0144 0147 **EDMS or** 8 8 දි වි 155 156 156 158 158 160 5 5 5 165 5 5 8 167 167 148 149 \$ \$ \$ 159 152 153 表 名 a пa na 147 151 멸멸 밀밀 R092670-PSY-3001 R076477-BIM-3004 R076477-BIM-3002 R092670-PSY-3006 R092670-PSY-3006 R092670-PSY-3001 R076477-SCA-3001 R076477-SCA-3001 R092670-PSY-3006 R092670-PSY-3007 R076477-SCA-3002 R092670-PSY-3006 R092670-PSY-3002 -3007 R092670-PSY-3007 R092670-PSY-3001 R076477-BIM-3004 R076477-BIM-3004 R092670-PSY-3007 na R076477-SCA-3001 R092670-PSY-3002 R092670-PSY-3001 R092670-PSY-3001 R092670-PSY-300 R092670-PSY-3001 R092670-PSY-3001 R076477-SCA-300 na PSY Protocol # R092670-PSY g 5 ם ā ä g g ğ 图图图 Бã Notification of PSY-3001 Study Termination Due to Efficacy, Letter: IRB Waiver Granted for 2/6/07 SN 150 Submission Letter: IRB Waiver Granted for 1/31/07 SN 148 Submission Email/Attachment: Meeting Request, Paliperidone Palmitate Email/Attachment: Official Meeting Minutes from 12/11/06 Response to RFI from DSI: Protocol R092670-PSY-3001 Email: SN 162 SAP - Question about Submission Study Between FDA and Local Trial Manager in Global Clinical Change in Protocol R092670-PSY-3001; Final Statistical Change in Protocol and Statistical Analysis Plan Request for a Type B CMC/Biopharmaceutics Pre-NDA FDA Div. Of Scientific Attairs: Telephone Contact Memo-Response to RFI: Copy of Protocol R092670-PSY-3001 Briefing Package for 4/18/07 Type B Pre-NDA Meeting etter: Official Meeting Minutes from 12/11/06 Telecon GCP Violations at Dr. Chaganiti's Site Under Protocol Request for a Type B. Pre-NDA Meeting Fax/Attachment: 7/15 Day Safety Report (K.Kiedrow) Fax/Attachment: 7/15 Day Safety Report (D.Bates) Response to FDA RFI: Additional Safety Information US-JNJFOC-20070203055 Initial 7/15 Day Report Email: 4/18/07 Type B Méeting Request Granted Minutes of December 11, 2006 Type C Meeting Email: Plan to Stop Study R092670-PSY-3001 Email: Reply to FDS's 4/5/07 Study Question Email: Request for Submission Information Request for Type B Pre-Phase 3 Meeting Fax: US-JNJFOC-20070204832 Initial Analysis Plan for R092670-PSY-3001 Site Closure: MedClin Research, Inc. RO-JNJFOC-20060503643 F-1 US-JNJFOC020070203055 F-2 US-JNJFOC-20070401462 Initial New Protocol; New Investigators US-JNJFOC020070201813 Initial New and Updated Investigators JS-JNJFOC-20070204832 F-2 US-JNJFOC-20070204832 F-1 Bipolar Development Program JS-JNJFOC-20070204832 JS-JNJFOC-200702030 IRB Waiver Request IRB Waiver Request R092670-PSY-3001 Email: S/162 SAP New Investigator New Investigator New Protocol Veeting na na na 2/6/2007 ā 5 E 8 8 8 8 8 8 8 區 ā 를 열 별 8 8 8 a a Contact General Correspondence Safety Report FDA Correspondence FDA Correspondence Information Amendmen FDA Correspondence FDA Correspondence FDA Correspondence FDA Correspondence Correspondence FDA Correspondence FDA Correspondence Submission Type FDA Correspondence FDA Correspondence FDA Correspondence FDA Correspondence Record of Contact Protocol Amendment Record of Contact IND Amendment IND Amendment ND Amendmen Safety Report Safety Report Salety Report Safety Report Safety Report Safety Report Safety Report Safety Repor Safety Repor 4/16/2007 4/17/2007 4/19/2007 2/26/2007 2/26/2007 2/26/2007 3/9/2007 3/15/2007 3/20/2007 3/30/2007 1/24/2007 2/2/2007 2/6/2007 2/11/2007 2/16/2007 2/16/2007 2/16/2007 2/26/2007 2/28/2007 3/5/2007 3/22/2007 3/26/2007 3/28/2007 3/30/2007 1/19/2007 1/23/2007 1/26/2007 1/31/2007 2/12/2007 2/15/2007 2/22/2007 4/6/2007 4/9/2007 4/11/007 2/16/2007 1/4/2007 1/9/2007 1/3/2007 1/9/2007

Salety Report na Briting States Report na Briting Package for ET/07 Correspondence na Fax: SN 171 (2nd sending of Salety Report na US-JNLFOC-20070405377 Salety Report na US-JNLFOC-20070405377 Salety Report na US-JNLFOC-20070404377 Salety Report na US-JNLFOC-200702040537 Salety Report na US-JNLFOC-200702040537 Salety Report na US-JNLFOC-200702040537 Salety Report na US-JNLFOC-200702040537 Salety Report na US-JNLFOC-200702040583 Salety Report na US-JNLFOC-200702040693 Protocol Amendment na Change in Protocol New Investigators na Email: No E-JNLFOC-2006120053 Salety Report na Email: Palperidone palmita Protocol Amendment na Change in Protocol JN Salety Report na Email: Palperidone palmita Noval No E-JNLFOC-2006120053 Salety Report na Email: Palperidone palmita Noval Nova		S ibmission Tone	Date of Contact	Description	Protocal #	SN#	Sequence #		
State Proportion				g Granted & Request for Meeting Pkg.	Bu	na	6733756	EDMS-PSDB-6/33/36	B L
Salary Report Ital CEANTEROCOGNOMOSON Tributes 1153 ROPERTY BIN 3004 171 0 173 FUN Conceptrations Ital For Sin 17 Circle standard and the control of the contr	_		T	20061200532	R076477-BIM-3004	22	0170	GW eCTD TOC	na
Salety Report Teach State	\neg	Safety Report	L C		R076477-BIM-3004	171	0171	GW eCTD TOC	na
Chief State	Т	Salety Report	0 0		Га	па	6793658	EDMS-PSDB-6793658	na
District Sportschip The Contraction of the Contra	4/30/2007	FUA Correspondence	2 2	Fax: SN 171 (2nd sending of fax)	na	па	.6793660	EDMS-PSDB-6793660	na
Construction In Surface Control Countries In Surface Countries	4/30/2007	FOA Correspondence	<u> </u>	Vinutes	na	na	6801969	EDMS-PSDB-6801969	na
Sales Proport In S.NIFFCQ-20070040477 is finish ROYART-BIM-3001 17.3 0.17.7 Sales Proport na U.S.NIFFCQ-20070040477 E-12 NF-5 ROYART-BIM-3001 17.3 0.17.7 Sales Proport na U.S.NIFFCQ-20070040478 E-12 NF-5 ROYART-BIM-3001 17.7 0.17.7 Canneal Consepondence na Brining Package for PATOL A Meeting Minuses SI-15.3 ROYART-BIM-3001 17.7 0.17.7 Sales Preport na U.S.NIFFCQ-20070040432 E-3 ROYART-BIM-3001 17.7 0.17.8 Sales Preport na U.S.NIFFCQ	5/3/2007	PDA COllespondence	2 2	7-Day F-1	R076477-BIM-3004	172	0172	GW eCTD TOC	na
International Personal Control Contr	5/4/2007	Safety Report	2 2	LIS-JNJFOC-20070404476 Initial	R076477-BIM-3001	173	0173	GW eCTD TOC	DB.
The contraction of the contrac	5/4/2007	Salety hepoti	2 6		R076477-BIM-3004	174	0174	GW eCTD TOC	na
Part Actual Correspondence	5/1/200/	Salety nepoli	2 00		H076477-BIM-3001	175	0175	GW eCTD TOC	กล
Construction Time Elivering Package for 67/07 CMA/CB/optamiscoultes Type B Infer 1076 1077 O177 Salety Report Consepondence na US_ALI/LOC-2007/2004829 F-3 178 0178 0178 Salety Report na Later I AND TO SSI VI 45 Statistical Review with Comments R076477-50A-3002 178 0178 Salety Report na User VIA DECONDORADIS II 45 Statistical Review with Comments R076477-50A-3002 179 0178 Salety Report na User VIA DECONDORADIS II 45 Statistical Review with Comments R076477-50A-3001 180 0178 Salety Report na User VIA DECONDORADIS II 45 Statistical Review Mind Statistical Review of the Comments o	5/8/2007	Sarety neport	2 60		na	na	6806260	EDMS-PSDB-6806260	na
Protected Amendment Page Protected Personal Perso	5/9/2007	General Correspondence	пa	CMC/Biopharmaceutics Type	па	176	0176	GW eCTD TOC	na
Salety Report na LASA NATION-C200702048328 F-3 177 0177 PARA Correspondence na Leiter: 14/007 SN 14.45 Stallard: Review with Comments FR02670-PSY-3000 177 0178 Canned Tourespondence na Leiter: 14/007 SN 14.45 Stallard: Report R076477-SCA-3000 179 0178 Canned Tourespondence na US-NUFFOCOZOO/ROBIN SIS VALABLE STALLARD FR076477-SCA-3000 180 0180 Salety Report na US-NUFFOCOZOO/ROBIN SIS VALABLE STALLARD FR076477-SCA-3000 180 0182 Protoco J Mandraffinent na Changa in Protocol: New Investigators na		•		pre-NDA Meeting	1000 000 1100	74.	77.10	CW ACTO TOC	eu
Protect Prot	5/9/2007	Safety Report	na	US-JNJFOC-20070204832 F-3	H0/64/7-5CA-3001		200	05-00-07 i etter	2
Salety Report na Mirulation of the Amening of the Att After Pre-NDA Meeting RODGATT/SCA-3002 178 0179 Salety Report na US_MUNE/OC.200702004032 F.4 RODGATT/SCA-3002 179 0179 Salety Report na US_MUNE/OC.20070204032 F.4 RODGATT/SCA-3001 180 0180 Salety Report na US_MUNE/OC.20070204032 F.4 RODGATT/SCA-3001 180 0182 Information Amendment na Chandidatchineal Femininary Comments for 6/1/07 Meeting na 182 0182 Flox Concespondence na France of US_Abusing Femininary Comments for 6/1/07 Meeting ROBGESTO-PSY-3000 183 0183 Flox Concespondence na France of US_Abusing Femininary Comments for 6/1/07 Meeting ROBGESTO-PSY-3007 184 0184 0184 Flox Concespondence na Enablication of Official Meeting Minutes Name Protocol Ameninean na 184 0185 0185 Flox Concespondence na Chandidatchineal Femilianary Comments for 6007 Meeting RODGAGACTA-PRACED PSY-3006 186 0185 Flox Concespondence	5/9/2007	FDA Correspondence	na	Letter: 1/4/07 SN 145 Statistical Review with Comments	H0926/0-PSY-300/	<u> </u>	24.70	CW OCTO TOC	82
Salety Report na US_AMLP COCROSOROSI 13 F-1 HORBATY SCANSOR 173 OFF87 Salety Report na US_AMLP COCROSOROSI 13 F-1 HORBATY SCANSOR 181 0180 Salety Report na Change in Protocol, New Investigators PROSECTO PSY-3006 181 0182 Floxocol Amendment na Change in Protocol, New Investigators PROSECTO PSY-3006 182 0182 Floxocol Amendment na Repaid (Color) PROSECTO PSY-3007 182 0183 Floxocol Amendment na New Protocol Protocol Amendment 183 0183 Floxocol Amendment na Repaid (Color) PROSECTO PSY-3007 183 0183 Floxocol Amendment na Inchange in Protocol Amendment 184 0183 0183 Floxocol Amendment na Learne (EOX)707 Official Minutes of the OT June 2007 Meeling ROSECTO-PSY-3007 187 0183 Floxocol Amendment na Change in Protocol Amendment na DESCRIPTOR OFFINATION OFFIN	5/11/2007	General Correspondence	па	Minutes of the 4/18/07 Pre-NDA Meeting	na Dozova za con	0 9	0470	GW ACTO TOC	eu
Salety Report na US_NANDO_2 2007/2016 100 pt 100 pt Protococl Amendment na US_NANDO_2 2007/2016 100 pt 100 pt Protococl Amendment na Include the Protocol (New Investigators) Include the In	5/16/2007	Safety Report	na	US-JNJFOC020070201813 F-1	H0/64/7-5CA-3002	8/8	0110	GW eCTD TOC	2
Protocool Amendment	5/22/2007	Safety Report	na	US-JNJFOC-20070204832 F-4	H0/64/7-5CA-3001	3 5	0100	GW eCTD TOC	e
Noncinical parametricinent na	5/24/2007	Protocol Amendment	na	Change in Protocol; New Investigators	HU926/U-131-3000	5 5	0101	GW ACTO TOC	80
FDA Correspondence Realizable Comments for 67/107 Meeling Registro-PSY-3001 Realizable Contest Registro-PSY-3001 Realizable Contest Registro-PSY-3001 Realizable Contest Registro-PSY-3001	5/25/2007	Information Amendment	na	Nonclinical Pharmacology Study Report	na	إق	0102	06.04.07 Email	ec
Record of Contact (piga20n) Protocol PSY-3007 Hale Protocol PSY-3007 Ina Debate Protocol Amendment na New Protocol New Investigators R092670-PSY-1008 184 0184 Protocol Amendment na New Protocol New Protocol 184 0184 Protocol Amendment na IRM War Protocol 184 0184 0185 FDA Correspondence na Letter: 0607/07 Official Meeling Minutes 180 186 0186 FDA Correspondence na Letter: 0607/07 Official Meeling Minutes of the 07 June 2007 Meeling 189 0186 Frotocol Amendment na Letter: 0607/07 Official Meeling Minutes of the 07 June 2007 Meeling 189 0186 Frotocol Amendment na Letter: 0607/07 Official Meeling Minutes of the 07 June 2007 Meeling 189 0186 Frotocol Amendment na DES.JMLFOC.2006 1200532 F-2 180 0186 General Correspondence na DES.JMLFOC.2006 1200532 F-2 180 0186 General Correspondence na DES.JMLFOC.2006 1200532 F-2	6/4/2007	FDA Correspondence	na	Email/Attachment: Preliminary Comments for 6/7/07 Meeting	na Feet Four	E I	118	CDAAC DCDB 6063412	80
Protocol Amendment na Change in Protocol; New Investigators House/SCN-PSY-100B 163 0163 Protocol Amendment na IRB Waker Request IRB Waker Request 185 0185 0185 FDA Correspondence na Email: NO 67,3265 3-Month Product Formulation: IND 76,932 na	6/8/2007	Record of Contact	6/8/2007	Protocol PSY-3001 "Rater" Qualifications	H0926/0-PSY-3001	E 5	0303412	COMOST SECTOR TO	5 6
Foreign	6/8/2007	Protocol Amendment	na	Change in Protocol; New Investigators	R092670-PSY-3007	3	0103	OW GOTO TOO	2 2
Character Correspondence na IRB Water Flequest IRB Water Regulators IRB Registron-PSY-100d <	6/14/2007	Protocol Amendment	na	New Protocol	H0926/0-PSY-1008	40,	0104	OCT OT OF WISH	200
FDA Correspondence na Ermail: NID 67,356 3-Month Product Formulation: IND 76,952 na Ina na FDA Correspondence na Lettler: O607/07 Official Meeting Minutes R092670-PSY-3006 166 0186 FOI correspondence na Change in Protocol R092670-PSY-3007 187 0186 Protocol Amendment na Change in Protocol Change in Protocol 189 0189 Salety Report na DE-JNLFOC-2006;1200532 F-2 R07 R07 R07 Annual Report na Reporting Period: 07/19/07 R02 R02 R07 Annual Report na Reporting Period: 07/20/06 - 07/19/07 R02 R02 R07 Annual Report na DE-JNLFOC-2006;1200532 F-3 R02 R02 R02	6/15/2007	General Correspondence	na		ᆚ	2	2010	06 15.07 Email	g
EDA Correspondence na Letter Object/Or Official Meeting Minutes FDA Correspondence na Letter Object/Or Official Meeting Minutes FODA Correspondence na Change in Protocol Amendment na Change in Protocol New Investigators Protocol Amendment na Change in Protocol New Investigators Protocol Amendment na Change in Protocol New Investigators Protocol Amendment na Change in Chan	6/15/2007	FDA Correspondence	па			g c	Z 2	06-13-07 Linian	eu
Protocol Amendment na Chamigae in Protocol Protocol Amendment na Chamigae in Protocol Protocol Amendment na Chamigae in Protocol Protocol Amendment na New Investigators Salety Report na DE-JUNE/OC-2000(1200322 F-2 Ceneral Correspondence na Email: Palipendone palmitate NDA Submission Plans Follocol Amendment na Chamigae in Protocol New Investigators Protocol Amendment na New Investigators Protocol Amendment na Reporting Period: O'1719/07 Protocol Amendment na Reporting Period: O'1719/07 Protocol Amendment na Reputitation Plans of Correspondence na Requestitor Protocol Amendment na New Investigators Protocol Amendment na Reputitation Plans of Correspondence na Requestitor Protocol Amendment na New Investigators Protocol Amendment na Reputitation Plans of Correspondence na Requestitor Protocol Amendment na New Investigators Protocol Amendment na Reputitation Plans of Correspondence na Requestitor Protocol Amendment na New Investigators Protocol Amendment na Reputitation Plans of Correspondence na Requestitor Protocol Amendment na New Investigators Protocol Amendment na New	6/29/2007	FDA Correspondence	na	Letter: 06/07/07 Official Meeting Minutes	DOCOCTO DOV 2006	186	0186	GW eSIG TOC	na
Candidation Control Amendment Charge in Protocol Amendment Charge in Charge in Protocol Amendment Charge in Protoc	7/31/2007	Protocol Amendment	па	Change in Protocol	B002570-F31-3000	26.5	0187	GW eSIG TOC	na
General Correspondence na Clarification of Official Minutes of the U.D.A Clarification of Official Minutes of the U.D.A R076477-BIM-3004 189 0189 Sately Report na DE_JNI/FOC-2006/1200532 F-2 na 190 0190 General Correspondence na Email: Paliperidone palmitate NDA Submission Plans na 190 0190 FDA Correspondence na Email: Paliperidone palmitate NDA Submission Plans R02650-PSY-1008 191 0191 Frotocol Amendment na Change in Protocol; New Investigators R02650-PSY-1008 192 0192 Annual Report na New Investigators R02650-PSY-1008 193 0193 Protocol Amendment na New Investigators R02650-PSY-3006 194 0194 Protocol Amendment na DE-JNLFOC-20061200532 F-3 R02650-PSY-3006 195 0195 Record of Contact 6/16/2004 Minutes of June 16,2004 CMC/Biopharmaceutics End of Record of Contact R02650-PSY-3006 196 0196 Record of Contact na Request for Proposed Proprietary Name Review R02660-PSY-3007	8/1/2007	Protocol Amendment	na	New investigators	1005-151-070760H	2 8	010	GW eSIG TOC	na
Safety Report na DE-JNLFOC-20061200532 F-2 R076477-BIM-3004 189 0189 General Correspondence na Email: Paliperidone palmitate NUA Submission for IT Testing na 190 0190 FDA Correspondence na Email: Paliperidone palmitate NUA Submission Plans na 191 0191 Protocol Amendment na Reporting Period: 07/20/06 - 07/18/07 178/20 193 0193 Protocol Amendment na Reporting Period: 07/20/06 - 07/18/07 R092670-PSY-100B 193 0193 Protocol Amendment na New Investigators R00-10-10-10-10-10-10-10-10-10-10-10-10-1	8/13/2007	General Correspondence	Ē	Clarification of Official Minutes of the U7 June 2007 Meeting -	<u> </u>	3	3		
General Correspondence na Sample Dataset Submission for IT Testing na 190 0190 General Correspondence na Emait: Paliperidone palmitate NDA Submission Plans R092670-PSY-1008 na na na Protocol Amendment na Apparation Plant Protocol Amendment na Reporting Period: 07720/06 - 07/19/07 R092670-PSY-1008 191 0191 0193 Annual Report na Reporting Period: 07720/06 - 07/19/07 R092670-PSY-3007 193 0193 0193 Annual Report na New Investigators R092670-PSY-3006 194 0194 0194 Frotocol Amendment na DE-JNLFOC-20061200532 F-3 R092670-PSY-3006 194 0194 Salety Report na DE-JNLFOC-20061200532 F-3 R062670-PSY-3006 194 0194 Record of Contact 6/16/2004 Minutes of June 16,2004 KMC/Biopharmaceutics End of Contact Annual Stability Data na 196 0196 Record of Contact 6/16/2004 Minutes of June 16,2004 CMC/Biopharmaceutics End of Contact R002670-PSY-3007 196 0196 Frotocol	70004 10007	Sefety Booort	60	DE-INIFOC-20061200532 F-2	R076477-BIM-3004	189	0189	GW eSIG TOC	na
Publication	2006/2010	General Correspondence	2	Sample Dataset Submission for IT Testing	na	190	0190	GW eSIG TOC	na
Protocool Amendment na Change in Protocol; New Investigators R092670-PSY-1008 191 0191 Annual Report na Reporting Period: 07/20/06 - 07/19/07 193 0192 0192 Annual Report na Reporting Period: 07/20/06 - 07/19/07 193 0193 0193 Protocol Amendment na New Investigators R002670-PSY-3006 194 0194 Protocol Amendment na DE-JNJFOC-20061200532 F-3 R002670-PSY-3006 195 0195 Record of Contact 6/16/2004 Minutes of June 16,2004 CMC/Biopharmaceutics End of Profession Palmitiate na 195 0196 Record of Contact 6/16/2004 Minutes of June 16,2004 CMC/Biopharmaceutics End of Profession Palmitiate na 196 0196 Information Amendment na Request for Proposed Product and Stability Data R002670-PSY-3006 198 0199 Protocol Amendment na Pharmacology/Toxicology R002670-PSY-3007 201 0202 Protocol Amendment na Statistical Analysis Plan for R022670-PSY-3007 R0202 0202 <tr< td=""><td>0/2//2001</td><td>EDA Correspondence</td><td>80</td><td>Email: Paliperidone palmitate NDA Submission Plans</td><td>na</td><td>Ŋä</td><td>Па</td><td>09-12-07 Email</td><td>na P</td></tr<>	0/2//2001	EDA Correspondence	80	Email: Paliperidone palmitate NDA Submission Plans	na	Ŋä	Па	09-12-07 Email	na P
Annual Report na Reporting Period: 07/20/06 - 07/19/07 na Reporting Period: 07/20/06 - 07/19/07 na New Investigators 192 0192 Protocool Amendment na New Investigators Rog26/70-PSY-3006 194 0194 Protocool Amendment na DE-JNJFOC-2006/1200532 F-3 ROG26/70-PSY-3006 195 0194 Record of Contact 6/16/2004 Minutes of June 16,2004 CMC/Biopharmaceutics End of Particles of Minutes of June 16,2004 CMC/Biopharmaceutics End of Particles of Minutes of June 16,2004 CMC/Biopharmaceutics End of Particles of Minutes of June 16,2004 CMC/Biopharmaceutics End of Particles of Minutes of June 16,2004 CMC/Biopharmaceutics End of Particles of Minutes of June 16,2004 CMC/Biopharmaceutics End of Particles of Minutes of June 16,2004 CMC/Biopharmaceutics End of Particles of Particles of Minutes of June 16,2004 CMC/Biopharmaceutics End of Particles of Particles of Minutes of June 16,2004 CMC/Biopharmaceutics End of Particles of Minutes of Minutes of June 16,2004 CMC/Biopharmaceutics End of Particles of Minutes of Minute	0/10/2007	Protocol Amendment	na	Change in Protocol; New Investigators	R092670-PSY-1008	191	0191	GW eSIG 10C	na
Protocol Amendment na New Investigators Protocol Amendment na New Investigators Protocol Amendment na New Investigators Safety Report na DE-JNJFOC-20061200532 F-3 Safety Report na CMC Drug Substance, Drug Product and Stability Data na New Investigators Information Amendment na Pharmacology/Toxicology Protocol Amendment na New Investigators Information Amendment na Statistical Analysis Plan for R092670-PSY-3007 Seneral Correspondence na Statistical Analysis Plan for R092670-PSY-3007 Seneral Correspondence na Statistical Analysis Plan for R092670-PSY-3007 Seneral Correspondence na Postmarketing Study Commitment Final Report: FDA Correspondence na Email/Attachment: IRB Waiver Granted FDA Correspondence na FDA FORD FORD FORD FORD FORD FORD FORD FORD	4/20/2007	Annual Report	па	Reporting Period: 07/20/06 - 07/19/07	na	192	0192	GW esig TOC	na
Protocot Amendment na New Investigators Safety Report na DE-JNJFOC-20061200532 F-3 Safety Report na DE-JNJFOC-20061200532 F-3 Safety Report na DE-JNJFOC-20061200532 F-3 Record of Contact 6/16/2004 Minutes of June 16,2004 CMC/Biopharmaceutics End of na New Investigators and Stability Data na New Investigators Information Amendment na Request for Proposed Proprietary Name Review R092670-PSY-3006 198 0199 Protocol Amendment na Pharmacology/Toxicology Protocol Amendment na New Investigators Information Amendment na Statistical Analysis Plan for R092670-PSY-3007 200 0200 Protocol Amendment na Statistical Analysis Plan for R092670-PSY-3007 201 0201 Protocol Amendment na Statistical Analysis Plan for R092670-PSY-3007 201 0201 General Correspondence na Postmarketing Study Commitment Final Report: na Postmarketing Study Commitment Final Report: na Postmarketing Study Commitment Final Report: na Postmarketing Study in the Rat Final Report na Emall/Attachment: IRB Waiver Granted R092670-PSY-1008 203 0203	11/1/2007	Protocol Amendment	na	New Investigators	R092670-PSY-3007	193	0193	GW 651G 1OC	110
Safety Report na DE-JNJFOC-20061200532 F-3 Record of Contact 6/16/2004 Minutes of June 16,2004 CMC/Biopharmaceutics End of na na Phase 2 Meeting for Paliperidon Palmitate Information Amendment na CMC Drug Substance, Drug Product and Stability Data na Request for Proposed Proprietary Name Review 197 0197 Protocol Amendment na Pharmacology/Toxicology Protocol Amendment na Pharmacology/Toxicology Protocol Amendment na Statistical Analysis Plan for R092670-PSY-3007 200 0200 Protocol Amendment na Statistical Analysis Plan for R092670-PSY-3007 201 0201 Protocol Amendment na Statistical Analysis Plan for R092670-PSY-3007 201 0201 General Correspondence na Postmarketing Study Commitment Final Report: na Postmarketing Study Commitment Final Report: na Postmarketing Study in the Rat Final Report na Emall/Attachment: IRB Waiver Granted R092670-PSY-1008 203 0203	11/2/2007	Protocol Amendment	ua	New Investigators	R092670-PSY-3006	3	\$ 200	SOL DISC MO	81
Record of Contact 6/16/2004 Minutes of June 16,2004 CMC/Biopharmaceutics End of Phase 2 Meeting for Paliperidon Palmitate na na Phase 2 Meeting for Paliperidon Palmitate Information Amendment na CMC Drug Substance, Drug Product and Stability Data na 196 0196 Protocol Amendment na Request for Proposed Proprietary Name Review R092670-PSY-3006 198 0198 Protocol Amendment na Pharmacology/Toxicology R092670-PSY-3007 200 0220 Protocol Amendment na New Investigators R092670-PSY-3007 201 0201 Protocol Amendment na Statistical Analysis Plan for R092670-PSY-3007 R092670-PSY-3007 201 0201 General Correspondence na Postmarketing Study Commitment Final Report: na na na FDA Correspondence na Emall/Mattachment: IRB Waiver Granted R092670-PSY-1008 203 0203	11/29/2007	_	na	DE-JNJFOC-20061200532 F-3	R076477-BIM-3004	195	calo	JOI DIS OF	000
Phase 2 Meeting for Palipendon Parmitate Information Amendment na CMC Drug Substance, Drug Product and Stability Data na Request for Proposed Proprietary Name Review na Reguest for Protocol Amendment na Pharmacology/Toxicology Rodge 199 0199 Protocol Amendment na Pharmacology/Toxicology Rodge 199 0199 Protocol Amendment na Statistical Analysis Plan for R092670-PSY-3007 201 0201 General Correspondence na Postmarketing Study Commitment Final Report: na Postmarketing Study Commitment Final Report: na Postmarketing Study Commitment Final Report: na Reguest Correspondence na Email/Attachment: IRB Waiver Granted Rogge 103 0203	12/6/2007		6/16/2004	Minutes of June 16,2004 CMC/Biopharmaceutics End of	g E	S S	Ē	12-00-07 Email	<u>=</u>
Information Amendment na CMC Drug Substance, Urug Product and Stability Data 197 0197 General Correspondence na Request for Proposed Proprietary Name Review 197 0197 Protocol Amendment na Pharmacology/Toxicology 199 0199 Protocol Amendment na Pharmacology/Toxicology 199 0199 Protocol Amendment na Pharmacology/Toxicology 199 0199 Protocol Amendment na Statistical Analysis Plan for R092670-PSY-3007 200 0200 Protocol Amendment na Statistical Analysis Plan for R092670-PSY-3007 201 0201 General Correspondence na Postmarketing Study Commitment Final Report: na Final Report na Final Report November Caranted Toxicity Study in the Rat Final Report November Caranted Final Report November Carante				Phase 2 Meeting for Paliperidon Palmitate		106	0196	GW eSiG TOC	na
General Correspondence na Hequest for Proposed Proprietary Name Hevrew R092670-PSY-3006 198 0198 Protocol Amendment na Pharmacology/Toxicology Information Amendment na Pharmacology/Toxicology Protocol Amendment na Pharmacology/Toxicology Protocol Amendment na Statistical Analysis Plan for R092670-PSY-3007 200 0200 Protocol Amendment na Statistical Analysis Plan for R092670-PSY-3007 201 0201 Protocol Amendment na Statistical Analysis Plan for R092670-PSY-3007 201 0201 General Correspondence na Postmarketing Study Commitment Final Report: na Postmarketing Study Commitment Final Report na Email/Attachment: IRB Waiver Granted Room R092670-PSY-1008 203 0203	12/11/2007		na	CMC Drug Substance, Urug Product and Stability Data	8 6	197	0197	GW eSIG TOC	na Bu
Protocol Amendment na New Investigators 199 0199 100 100 100 100 100 100 100 10	12/21/2007		па	Request for Proposed Proprietary Name neview	D000670, DCV.3006	199	0198	GW eSIG TOC	na
Information Amendment na Pharmacologyi oxicology Protocol Amendment na New Investigators Protocol Amendment na Statistical Analysis Plan for R092670-PSY-3007 201 0201 Protocol Amendment na Statistical Analysis Plan for R092670-PSY-3007 201 0201 General Correspondence na Postimarketing Study Commitment Final Report: Developmental Toxicity Study in the Rat Final Report FDA Correspondence na Emall/Attachment: IRB Waiver Granted R092670-PSY-1008 203 0203	12/27/2007	Protocol Amendment	na	New Investigators	2000 10 10 10 10 10 10 10 10 10 10 10 10	9	0199	GW eSIG TOC	na
Protocol Amendment na New Investigators Protocol Amendment na Statistical Analysis Plan for R092670-PSY-3007 201 0201 General Correspondence na Postmarketing Study Commitment Final Report: na Developmental Toxicity Study in the Rat Final Report na Final/Matachment: IRB Waiver Granted R092670-PSY-1008 203 0203	1/9/2008	Information Amendment	gu	Pharmacology/ Loxicology	R092670-PSV-3007	200	0200	GW eSIG TOC	na
Protocol Amendment na Statistical Analysis Plan for Huszeviu-15 - 3007 General Correspondence na Postmarketing Study Commitment Final Report na Protective Study in the Rat Final Report na Final/Matachment: IRB Waiver Granted na Final/Matachment: IRB Waiver Granted R092670-PSY-1008 203 0203	1/15/2008	Protocol Amendment	na	New Investigators	P002670-PSV-3007	203	0201	GW eSIG TOC	g
General Correspondence na Posimarketing Study Commitment Final Meport. Developmental Toxicity Study in the Rat Final Report na Email/Attachment: IRB Waiver Granted na Email/Attachment: IRB Waiver Granted Naw Investigators Developmental Toxicity Study in the Rat Final Report na	1/23/2008	Protocol Amendment	na	Statistical Analysis Plan for H092670-PSY-3007	1005-15-1-010260H	200	0202	GW eSIG TOC	g
FDA Correspondence na Email/Attachment: IRB Waiver Granted na	1/25/2008	General Correspondence	g U	Postmarketing Study Commitment Final heport: Developmental Toxicity Study in the Rat Final Report	<u> </u>	202			
Honorest Honorest Honorest Honorest 1000	4/30/2008	EDA Correspondence	la Ua	Emall/Attachment: IRB Waiver Granted	na	па	na	01-30-08 Email	na
Doctors American Signature and	1/30/2000	Protocol Amendment	8	New Investigators	R092670-PSY-1008	203	0203	GW eSIG TOC	g

	Date of			3	EDMS or	Hyparing	Загежаў месегрі
Submissidh Type	Confact	East ON 0004		å _	na	02-08-08 Fax	na
7	200	Fax. SN 0204 D.F. IN IEOC. 20070701878 Initial	R092670-PSY-3007	204	0204	GW eSIG TOC	na
7	ā 6	New Investigators	R092670-PSY-3006	205	0205	GW eSIG TOC	na
2/28/2008 Protocol Amendment	n c	New Investigators	R092670-PSY-3007	206	0206	GW eSIG TOC	па
2/28/2008 Protocol Amendment	<u> </u>	Change in Protocol: New Investigators	R092670-PSY-3006	207	0207	GW eSIG TOC	na
1	23	US-JNJFOC-20070204832	R076477-SCA-3001	208	9020	GW eSIG TOC	na
Τ'''	Bu	Email: SN 201 Study R092670-PSY-3007 Statistical	R092670-PSY-3007	Па	B	04-09-08 Email	na
	- 8	Analysis Plan	R092670-PSY-1008	209	0209	GW eSIG TOC	na
\neg	na	Crange II Floreco	E C	209	0208	GW eSIG TOC	na
4/21/2008 Information Amendment	2 0	Emoil/Attachmost: Statistical Analysis Plan	R092670-PSY-3007	na	na	04-28-08 Email	กล
	ng L	Email/Attachmente: Study Ouestion	Da	na	na	07-14-08 Email	na
_	E I	EIIIali/Ariacilileliis. Study Question	B076477-PSZ-3001	210	0210	GW eSIG TOC	na
_	3 29	Time B End of Dhese 2/Pre-Phase 3 Meeting Benilest	eu.	211	0211	GW eSIG TOC	па
_	<u>a</u>	Type D Ello-U-F 1836 ZF 18-1 1836 J McCarig Tegaco.	R076477-PSZ-3001	212	0212	GW eSIG TOC	па
_	<u>a</u> 5	IN IN IECC. 20080704122 E.1	R076477-PSZ-3001	213	0213	GW eSIG TOC	na
8/29/2008 General Correspondence	na		<u> </u>	214	0214	GW eSIG TOC	กล
	 	Phase 3 Meeting		$\frac{1}{1}$			na
45 T	OCs are only	zavanabie electronicany.	P002670, PCV-1008	215	0215	GW eSIG TOC	na
9/16/2008 Protocol Amendment	na	Change in Protocol	0001 10 10 10 10 10 10 10 10 10 10 10 10	216	0216	GW eSIG TOC	na
9/19/2008 Annual Heport	na S	helponing remou. 072007 - 0771300	B076477-SCA-3002	217	0217	GW eSIG TOC	na
9/23/2008 Salety Report	2 2	Updated Clinical Protocol Summary for 07Oct2008 Type C	па	218	0218	GW eSIG TOC	na
	<u></u>					1 00 00	
9/30/2008 FDA Correspondence	na	Preliminary Comments for Oct 7 Meeting		па	па	09-30-08 Email	na
1	na	Email/Attachments: Paliperidone palmitate Meeting Minutes		na	na	10-16-08 Email	na
-	na	Minutes of the 7Oct08 End of Phase 2/Pre-Phase 3 Mtg.	na	219	0219	GW esig IOC	EE.
	na	Email/Attachment from FDA: PSP Issue Follow-up	na	па	na	11-06-08 Email	Cape odoo ogic
_	па	DE-JNJFOC-20061200532 F-4	R076477-BIM-3004	220	0220	GW ests 100	0/300-0270 eolo
1	na	Updated Investigator's Brochure, Edition 9, 02/25/08	na na	122	0221	GW ests 100	67356-0221 e31G
4/13/2009 Protocol Amendment	na	New Protocol	H0926/0-SCH-3004	777	0000	OOL DISO WE	67356-0222 aSIG
_	na	Justification for Suicidality Assessment	חממט במט רביי סביטר	2220	0222	GW esig TOC	67358-0223 eSIG
	na	PL-JNJFOC-20081000072 Initial 7-Day Report	H076477-PSZ-3002	5253	0223	CAN GOIG TOC	67356.0924 eSIG
	na	Response Requested: Approval of Suicidality Assessment Plans for the Palipendone Palmitate Development Programs and Approval to Use the ISST-Plus Scale	S .	524	0224	OO DIGG MS	01030-0574
4 inglinone EDA Correspondence	e c	Fmail to FDA: Palmitate Suicide Assessment Plans	na	па	na	04-23-09 Email	
	ed	PL-JNJFOC-20081000072 F-1	R076477-PSZ-3002	225	0225	GW eSIG TOC	67356-0225_eSIG
_	2	FDA Letter: Suicide Assessment with ISST-plus	R092670-SCH-3004	na	na	06-02-09 Letter	na
Т	9	New Investigators	R092670-PSY-3006	226	0226	GW eSIG TOC	
1_	g	Chemistry, Manufacturing & Controls	R092670-SCH-3004	227	0227	GW eSIG TOC	67356-0227_eSIG
				+			
				1			
				_			
				<u> </u>			
				<u> </u>			
	+						

NDA 22-264 INVEGA SUSTENNA (paliperidone palmitate) (R092670) Long-Acting Injection (JNJ-16977831)

Oate Submission Type	Contact	Description	A CONTRACTOR OF THE PARTY OF TH			
	na	cation	na	0000	GW eSIG TOC	ВП
. 1	e na	Desk Copy - Review Aid	na	na.	10-26-07 Desk Copy	na
	na	Letter: NDA Receipt Acknowledgement	na	EZ.	11-07-07 Letter	na
	na	Email: Information Request	กล	na	12-05-07 Email	па
j	na	Email/Attachment: Request for Datasets	na	ВП	12-07-07 Email	g
12/11/2007 NDA Amendment	ทล	Response to FDA Request for Carcinogenicity Tumor Dataset	na	1000	GW eSIG TOC	na na
12/19/2008 FDA Correspondence	na	Emait: 3-Month Pali Palmitate IND 76,952 Plans and NDA 22-264 Tradename Question	na	ua	12-19-07 Email	na
12/21/2007 General Correspondence	na	Request for Proposed Proprietary Name Review	na	0005	GW eSIG TOC	na
12/21/2007 FDA Correspondence	L	Email/Attachment: Filing Communication Letter	na	na	12-21-07 Email	na na
12/21/2007 FDA Correspondence	na	Letter: Filing Communication Letter	БП	na	12-21-07 Letter	na
1/9/2008 General Correspondence	na	Response to FDA Filing Communication: Request for Carcinogenicity Data	na	£000	GW eSIG TOC	na
1/10/2008 FDA Correspondence	BU	Email/Attachment: Reformatted Tumor Dataset	na	g	01-10-08 Email	ec
	ВU	Email/Attachment: Review of the NDA	na	Da Da	01-30-08 Email	eu
_	na	Email: Dystonia Class Labeling Follow-up to Our Earlier Discussion	na	na	02-07-08 Email	gu
2/11/2008 FDA Correspondence	na	Email/Attachment: RISPERDAL and INVEGA Clinical Development Program Analyses	a	ກສ	02-11-08 Email	na
2/25/2008 Safety Update	na	4-Month Safety Update	gu	0004	GW eSIG TOC	na
2/21/2008 General Correspondence	L	Response to FDA RFI: SAS Data Sets for Study R092670-PSY-3001	na	9000	GW eSIG TOC	na
	กล	Email/Attachments: 4-Month Safety Update-Response to Email Dated 14 Feb for SAS Data Sets	เกล	ยน	02-25-08 Email	กล
	g	Transfer of NDA Ownership	na	. 9000	GW eSIG TOC	. na
	\dashv	Transfer of NDA Ownership	กล	0007	GW eSIG TOC	na
	na	Email/Attachment: Metabolic Parameter Request	na	Ra	03-21-08 Email	na
_	ла	Email: Voice Mail Follow-up: Study R092670-PSY-3001	na	na	04-09-08 Email	na
	na	Letter; Request for CMC Information	na	па	04-22-08 Letter	na
_	4	Email: CMC Questions	na	па	04-30-08 Email	na
_	4	Response to FDA RFI: Study Center Information	na	8000	GW eSIG TOC	na
_	4	Email: Request for Update on Information Request Response	па	na	05-12-08 Email	na
	\downarrow	Response to FDA RFI: IVIVC Information	Ē	6000	GW eSIG TOC	na
т.	па	Email: Follow-up Information on Study R076477-PSY-3001	ā	na	05-13-08 Email	na
5/16/2008 FDA Correspondence	па	Email: Biopharmaceutics Telecon	g	na	05-16-08 Email	na
S/10/2008 FDA Correspondence	e C	Email: CMC Hesponse Timeline	g	na Pa	05-18-08 Email	na
_	\downarrow	Status of Ongoing Study R076477-PSY-3001 Pending NDA 22-264	2 2	5050	GW ASIG TOC	E 0
_	L	Desk Cook - Beview Aid	9 6	ec	05-21-08 Deek Cons	27.0
_	L	Email/Attachment: Biopharm Teleconference on 19 May 2008	2 2	na	05-22-08 Email	na
5/23/2008 FDA Correspondence	na	Email/Attachment: Biopharm Teleconference on 19 May 2008	na.	па	05-23-08 Email	na
	na	Email: Information Request	na	na	05-23-08 Email	na
		Email: Receipt of Questions	na	na	05-27-08 Email	na
_		Minutes of 19 May 2008 Teleconference	na	0011	GW eSIG TOC	Пâ
	_	Response to FDA RFI: CMC Request of 22 April 2008	na	0012	GW eSIG TOC	na
П	-	Response to FDA RFI: Adverse Event Rates and Revised Table 1	na	0013	GW eSIG TOC	na
6/3/2008 General Correspondence	<u>a</u>	Response to FDA RFI: IVIVC Supporting Data and Computer Programs	na	9014	GW eSIG TOC	na
6/3/2008 FDA Correspondence	ВП	Email: FDA Request for Samples of Pali Palmitate Drug Product	na	na	06-03-08 Email	na

na 22264-0025_eSIG ā E E E E пã ā g Ē na ā a 2 g g Ę na na ā na na 5 5 5 E a Ē ā 5 8 B na 8 g ā GW eSIG TOC 07-11-08 Email GW eSIG TOC 06-23-08 Email 06-23-08 Email 06-25-08 Email 06-27-08 Email 06-30-08 ROC GW eSIG TOC 07-02-08 Email 07-02-08 Email 07-29-08 Letter GW eSIG TOC 08-15-08 Email 08-15-08 Email GW eSIG TOC 09-02-08 Email GW eSIG TOC GW eSIG TOC 12-01-08 Email GW eSIG TOC 06-25-08 Email GW eSIG TOC 07-10-08 Email 06-16-08 Email 01-23-08 Email 06-26-08 Email 08-25-08 Letter 08-26-08 Email GW eSIG TOC 06-23-08 Emai GW eSIG TOC 07-29-08 Email 08-21-08 Email 08-21-08 Email 09-26-08 Email 06-04-08 06-11-08 na 8615438 0017 na 0015 0016 a 0000 8100 na 9023 10024 0024 0025 g 8 8 8 8 8 8 ā a 2002 na 2002 **a** a ā g 8 8 8 ã 혈멸 na a 8 2 E 5 5 **B B** na ā **a a a** B 2 2 2 E 腔 88888 g 5 5 S a a 2 2 2 2 Email/Attachment: Additional Info Request (Clinical)
Email/Attachments: Response to RFI for Information: Investigator Chaganti Follow Up on Studies R092670-PSY-3001, R092670-PSY-3002, R092670-PSY-1004; Response Requested: for Revised R092670-PSY-3002 Report Email: Pediatric Study Requirements Summary of 30 June 2008 FDA/J&JPRD Telecon - CMC Request for FDA to Review Information for Use Leaflet & Packaging Color Request for Meeting: Type A Meeting: Resubmission Contents to Address Response to RFI: CMC Request of 30 June 2008

Email/Attachments: Status of Data QC Review - Summary Table
Response to FDA RFI: Pediatric Waiver Request
Follow-up Information on Study R092670-PSY-1004; Agreement for Data
Erratum to Clinical Study Report R092670-PSY-1004 Email: Non-Objection to Amended CSR Approach for R076477-PSY-3001 Email: Additional Info Request (Clinical)

Email: Update - R092670-PSY-3001, PSY-3002, & PSY-1004

Email/Attachments: Response to RFI for Information: Investigator Glass Email/Attachment: Request Additional Information Email/Attachments: Summary of 30June2008 Telecon: DMF 20902 and NDA 22-264 and Available Responses to Questions Email: Addition of "orude" for Identification and CMC RA Responsibility Email/Attachment: NDA 22-264 Proprietary Name Still Under Review Response to FDA RFI: CMC Request of 20 May 2008 Emait: Clinical Information Request
Emait/Attachment: Clinical Information Request
Response to FDA RFI: Package Insert and Adverse Events in Acute Background Briefing Package for 21 Nov 2008 Type B Meeting Email/Attached Letter: 11/21/08 Meeting Minutes Sponsor's Minutes from the 21Nov2008 NDA Resubmission Meeting Email: Trademark Name INVEGA SUSTENNA Is Acceptable Response to FDA RFI: CMC Request of 29 July 2008 Email: Type B Meeting Request Granted for 11/21/08 Email: Information Request - Receipt of Questions Email from FDA: Request Additional Information Email: Request for Phone/Fax Info Letter: NDA Cannot Approve Letter FDA's Complete Response Letter Letter: Information Request: CM(Email/Attachment: Action Letter are only available electronically and R092670-PSY-3002 Email: Peds Question Email: Action Shange na 6/30/2008 222222222 8 8 na 멸멸 ğ 8 8 8 8 8 8 8 8 8 8 2 2 2 na ā 22222 na Note: Effective 09/01/08, emails and ROCs FDA Correspondence General Correspondence General Correspondence General Correspondence FDA Correspondence General Correspondence General Correspondence FDA Correspondence General Correspondence 1/13/2009 |General Correspondence General Correspondence General Correspondence General Correspondence FDA Correspondence 8/12/2008 | General Corresponder 8/15/2008 | FDA Correspondence Record of Contact NDA Amendment 6/25/2008 9/26/2008 9/2/2008 7/2/2008 6/18/2008 6/23/2008 6/26/2008 6/27/2008 7/10/2008 7/11/2008 8/15/2008 8/26/2008 6/23/2008 6/25/2008 7/15/2008 8/20/2008 8/21/2008 8/21/2008 8/25/2008 12/1/2008

na 22264-0027_eSIG 22264-0026_eSIG 22264-0028_eSIG 22264-0029_eSIG eSIG na 22264-0031_eSIG 22264-0032_eSIG 22264-0033_eSiG 22264-0034_eSIG 22264-0030 Ē Ę ē ğ ā g пa na กล g ĕ ğ g g B Ē 200 8 B GW eSIG TOC GW eCTD TOC 05-14-09 Email GW eSIG TOC 05-15-09 Email 05-15-09 Letter 03-30-09 Email 04-03-09 Email 04-24-09 Letter 05-01-09 Email 02-06-09 Email GW eSIG TOC 05-18-09 Email GW eSIG TOC 05-25-09 Gen Cor 05-26-09 Email 06-08-09 Email GW eSIG TOC 06-15-09 Email 06-15-09 Email 06-16-09 Email 02-13-09 Letter 05-20-09 Email 06-01-09 Email 06-05-09 Email GW eSIG TOC 02-13-09 Email 05-05-09 Email GW eSIG TOC GW eSIG TOC 05-27-09 Email 06-08-09 Email 06-04-09 Email 06-11-09 Email 80028 80028 80028 na 0032 0030 na na na na na 0026 0034 8 5 Z 0033 ğ 멸멸 2 2 g g na na 밀밀 g ŝ 8 a a a a ģ **B B** B g 2 2 a a 2 2 g g B. 8 8 8 8 8 æ Па g B 등 na a a ล 5 5 5 5 E 멷 2 Approved Proprietary Name Email/Attachment from FDA: 2/2/09 Submission is a Class 2 Resubmission Email from FDA: Review Team RFI - "Mock-up" Copy of Proposed Syringe Resubmission: Sponsor's Responses to FDA's Complete Response Letter Email/Attachment to FDA. Response to Request for Location of Narratives for Elevated Liver Enzymes Email/Attachments to FDA: Janssen Pharmaceutica N.V. Samples to FDA Email from FDA: Tradename Submission Request for Proprietary Name Review: Re-review of Previous Tentatively Email to FDA: Mock-ups - RE: SAS Code for PSP Analysis - Information Email from FDA: Request for Information - Liver Enzymes Email from FDA: Information Request for Additional Financial Disclosure Email/Attachments to FDA: Pre-Launch Activities Importation Request Email to FDA: Mock-ups of INVEGA SUSTENNA Commercial Product Response to RFI: Clinical Study Report PALIOROS-PSZ-1001 Email to FDA: Information Request FDA Letter: Proposed Proprietary Name, INVEGA SUSTENNA, Responst to RFI: CM&C Response to Information Request Letter of 23 Email/Attachment to FDA: Information Request · Xu et.al Publication Response to RPI: Efficacy Subgroup Analyses for R092670-PSY-3007 Response to RFI: SAS Programs for PSP Analyses
Email/Attachment to FDA: SAS Code for PSP Analyses - Information Email from FDA: Information Request (Simulation Code and Dataset) Email to FDA: Information Request (Simulation Code and Dataset) Email from FDA: Information Request (Simulation Code and Dataset) FDA Letter: CMC Reviewer RFI Email from FDA: DMF 20902 Amendment - Additional Stability Data Email from FDA: RFI - DMF 20902 Vacuum Leak Test Method Email/Attachments to FDA: DMF 20902 Response to Request from Email from FDA: Re: Janssen Pharmaceutica N.V. Samples to FDA Email/Attachment to FDA: UPS Tracking Numbers for Samples FDA Letter: 02/03/09 Submission Receipt Acknowledgement Response to Request for Information: CMC Drug Substance Certification for Delay of Posting Clinical Trial Results on Pre-Launch Activities Importation Request Amendmen Pre-Launch Activities Importation Reques Email/Attachments: Information Request with a 6 Month Review Cycle Request for NDA 22-264 Request for NDA 22-264 www.ClinicalTrials.gov Included for Cork and Carton Kit Information Acceptable April 2009 60/08/80 na **8 8 B B B** 8 8 a a a 2 2 2 B na 88888 g ā 8 B ä 5 S 222222 g FDA Correspondence General Correspondence FDA Correspondence FDA Correspondence General Correspondence General Correspondence General Correspondence General Correspondence General Correspondence General Correspondence FDA Correspondence Offrer 2/24/2009 5/18/2009 4/24/2009 5/1/2009 5/15/2009 5/15/2009 5/15/2009 6/15/2009 6/15/2009 6/16/2009 2/13/2009 3/30/2009 5/14/2009 5/22/2009 5/27/2009 6/11/2009 5/6/2009 2/13/2009 5/20/2009 5/25/2009 6/1/2009 2/3/2009 2/11/2009 5/26/2009 6/8/2009 6/6/5009 4/3/2009 5/5/2009 6/4/2009 6/2/5009 6/8/2009

กล	na	กล	na	22264-0035_eSIG	22264-0036_eSIG	па			
06-16-09 Email	06-16-09 Email	06-16-09 Email	06-19-09 Email	GW eSIG TOC	GW eSIG TOC	06-22-09 Email			
na	па	na	na	. 0035	9800	na			
na	na na	na	па	na	na	па			
Email/Attachments to FDA: Amended PLAIR - NDA 22-264 Pre-Launch Activities Importation Request	Email/Attachment to FDA: Amended PLAIR - NDA 22-284 Pre-Launch Activities Importation Request Response	Email to FDA: Information Request (Simulation Code and Dataset) Update	Email/Attachments from FDA: Amended PLAIR is Acceptable	Response to RFI: Data Files and Control Script Files Used to Conduct Simulations	Response to RFI: Financial Disclosure Clinical Investigators	Emoil/Attachments to FDA: Response to RFI: Data Sets and Financial Disclosures		•	
25	g	22	na	па	ยบ	na			
6/16/2009 FDA Correspondence	6/16/2009 FDA Correspondence	6/16/2009 FDA Correspondence	6/19/2009 FDA Correspondence	6/22/2009 Amendment to Pending Application	6/22/2009 Amendment to Pending Application	6/22/2009 FDA Correspondence			
6/16/2009	6/16/2009	6/16/2009	6/19/2009	6/22/2009	6/22/2009	6/22/2009			

.

De M